Health Choice Arizona Medication

Prior Authorization Criteria

January 01, 2018

Health Choice Arizona Prior Authorization Form

Please find on the last page of this document.

Prior Authorization Request Contact Information

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List of Step Therapy Criteria Medications

Criteria documents start on page 3

- Advair, Dulera, Flovent and Symbicort
- Tolterodine
- Tolterodine ER
- Myrbetriq

STEP THERAPY PHARMACY COVERAGE POLICY

Drug Class	Targeted Drugs	Requirement
BRONCHODILATOR AGENTS	ADVAIR DISKUS, DULERA, FLOVENT, AND SYMBICORT	Trial of one steroid inhalers: Qvar, Pulmicort Respules or Asmanex
URINARY ANTISPASMODICS	TOLTERODINE	Trial of oxybutynin
URINARY ANTISPASMODICS	TOLTERODINE ER	Trial of oxybutynin and tolterodine
URINARY ANTISPASMODICS	MYRBETRIQ	Trial of all generic urinary antispasmodics (i.e. oxybutynin, tolterodine, trospium chloride)

HEALTH CHOICE ARIZONA MEDICATION PRIOR AUTHORIZATION CRITERIA

Contents

Brand Name	Generic Name
ACTIMMUNE	Interferon gamma-1b

CRITERIA FOR COVERAGE/NONCOVERAGE

ACTIMMUNE/Interferon gamma-1b will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The member must be clinically diagnosed with one of the following conditions:
    - Chronic Granulomatous Disease
      OR
    - Severe, malignant osteopetrosis

Approval will be granted for 6 months (if no improvement within 6 months discontinue treatment)

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 11/2016
Criteria last updated: 11/2016

Brand Name	Generic Name
ADCIRCA	tadalafil

CRITERIA FOR COVERAGE/NON-COVERAGE

ADCIRCA/ tadalafil will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The member must have the following diagnosis including documentation from the member's medical records;
  - **Pulmonary arterial hypertension** (PAH) , WHO group I, NYHA class II-III

AND

- Medication must be prescribed by a Cardiologist or Pulmonologist

AND

- The member is 18 years of age and older

AND

- The member must have tried and failed or have a documented intolerance to sildenafil

AND

- **IF** member has a positive vasoreactivity test, must have tried and failed a calcium channel blocker

Approval will be granted for 12 months unless shorter duration requested by prescriber.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last updated: 03/2017

Covered Name	Reference Brand or Generic Name
adefovir	HEPSERA
TYZEKA	telbivudine

CRITERIA FOR COVERAGE/NON-COVERAGE

HEPSERA/adefovir, TYZEKA/telbivudine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member is 12 years of age or older (for adefovir) or 16 years of age or older (for TYZEKA)
2. Member has a diagnosis of chronic hepatitis B
3. Member is HBsAg-positive for at least 6 months
4. For HBeAg-positive members, serum HBV DNA > 20,000 IU/mL (105 copies/mL) and For HBeAg-negative members, serum HBV DNA > 2,000 IU/mL (104 copies/mL)
5. Member has evidence of persistent elevations in serum aminotransferases (alanine transaminase[ALT] or aspartate aminotransferase [AST]) at least 2 times the upper limit of normal **OR** histologically active disease (i.e.necroinflammation on biopsy)
6. Due to lack of resistance when used long term , member must have tried and failed treatment with a preferred alternative (peginterferon, entecavir, or tenofovir disoproxil fumarate)
7. For adefovir, the medication will be used in combination with lamivudine (to reduce drug-resistance)
8. For TYZEKA, the medication will not be co-administered with pegylated interferon alfa-2a

Authorization for continued use shall be reviewed after 12 months to confirm the following:

- HBeAg negative members have not had HBsAg clearance. Continued approval x 12 months
- HBeAg positive members, detectable HBV DNA and have not been anti-Hbe for at least 6 months. Continued approval x 12 months

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed: 11/2016

Brand Name	Generic Name
AMITIZA	lubiprostone

CRITERIA FOR COVERAGE/NON-COVERAGE

Amitiza is a chloride channel activator indicated for the treatment of chronic idiopathic constipation in adults, the treatment of irritable bowel syndrome (IBS) with constipation in women ≥ 18 years old and for the treatment of opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation. The effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids such as methadone has not been established.

Amitiza will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:
   a. For the treatment of chronic idiopathic constipation in adults that meets all of the following:
      1. Prescribed by or in consultation with a specialist in gastroenterology and other possible causative conditions have been appropriately treated first and documented (organic or neurologic conditions).
      2. Clinically diagnosed documented chronic idiopathic constipation, defined as less than **three spontaneous bowel movements** (SBMs) per week, on average, with **two** or more of the following symptoms of constipation for at least **six months**:
         - Very hard stools for at least a quarter of all bowel movements.
         - Sensation of incomplete evacuation following at least a quarter of all bowel movements.
         - Straining with defecation at least a quarter of the time.
   b. For the treatment of IBS with constipation in women ≥ 18 that meets all of the following:
      1. Prescribed by or in consultation with a specialist in gastroenterology and IBS has been first appropriately treated.
      2. Clinically diagnosed documented IBS, defined as abdominal pain or discomfort occurring over at least **six months** with **two** or more of the following:
         - Relieved with defecation.
         - Onset associated with a change in stool frequency.
         - Onset associated with a change in stool form.
   c. For the treatment of opioid-induced constipation in adults with chronic non-cancer pain defined as less than **three SBMs** per week, on average, with **two** or more of the following symptoms of constipation for at least **six months** and is currently taking an opioid verified per prescription claims history.
      - Very hard stools for at least a quarter of all bowel movements.
      - Sensation of incomplete evacuation following at least a quarter of all bowel movements.
      - Straining with defecation at least a quarter of the time.

2. Trial and failure of **all** of the following listed below. Documentation must include dates of trial and failure in the chart notes and supported by prescription claims history. Trial must consist of a minimum of 30 days.

   a. An increase in dietary fiber by food and by fiber supplements (Metamucil).
   b. One saline laxative, such as milk of magnesia or magnesium citrate.
   c. Lactulose.
   d. Polyethylene glycol (Miralax).
   e. One stimulant laxative, such as sennosides (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada. If oral is ineffective then suppositories, such as glycerin or bisacodyl, must be attempted.

Failure defined as a documented no change in baseline symptoms as identified in the approvable diagnoses for #1 (a, b, or c).
Intolerance does not include the products having a bad taste.

Approval length: 6 months initially then 12 months thereafter.

Continuation criteria:

1. Consistent prescription claim history. If non-adherence is observed then re-review will occur of the request to determine if criteria for chronic constipation diagnosis is still met.
2. Documentation member is receiving a positive clinical response defined as an increase in SBMs per week.

References:

1. Amitiza Prescribing information. Deerfield, IL Takeda Pharmaceuticals. Rev Aug 2017.
2. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017.
3. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017.
4. Bharucha A, Pemberton, JH, et al. American Gastroenterological Association Technical Review on Constipation. *Gastroenterology* 2013;144:218-238.

Criteria reviewed: 07/2017
Criteria revised: 9/2017

Brand Name	Generic Name
ANZEMET	dolasetron

CRITERIA FOR COVERAGE/NON-COVERAGE

ANZEMET / dolasetron will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:
    a. Prevention and treatment of postoperative nausea and vomiting (PONV)
    b. Prevention of radiation-induced nausea and vomiting
    c. Prophylaxis of chemotherapy-induced nausea and vomiting due to moderate to high emetogenic potential chemotherapy
2. An inadequate response, intolerance, or contraindication to a trial of ondansetron and granisetron
3. Member must have normal potassium and magnesium levels prior to Anzemet treatment

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed: 11/2016

Brand Name	Generic Name
ARANESP	darbepoetin alfa
PROCRIT	epoetin alfa
EPOGEN	epoetin alfa

CRITERIA FOR COVERAGE/NON-COVERAGE

The above medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:

    a. Anemia associated with chronic kidney disease (includes those on dialysis and not on dialysis)
    b. Anemia in patients on myelosuppressive chemotherapy; where there is a minimum of at least two additional months of planned chemotherapy
    c. Anemia in Zidovudine-treated HIV infected patients
    d. Reduction of allogeneic RBC transfusion in patients undergoing elective non-cardiac, nonvascular surgery (Epogen/Procit only)
    e. Well accepted off-label indications such as treatment of anemia of chronic disease (i.e. rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel diseases), anemia associated with myelodysplastic disease, and treatment of anemia in patients with Hepatitis C that are receiving ribavirin therapy

2. The member has a hemoglobin level as designated below: (required lab tests for hemoglobin must be performed within 90 days of the authorization request)

    a. Hemogloblin less than 10 g/dl for patients receiving Cancer Chemotherapy or patients with Hepatitis C with anemia that is secondary to ribavirin and interferon-alfa therapy
    b. Hemoglobin is less than 12 g/dl and Hematocrit less than 33 for other approved FDA indications in addition to supporting statement of diagnosis from physician (lab results must be within 90 days of the authorization request)
    c. Hemoglobin is greater than 10 g/dl but less than or equal to 13 g/dl within the previous 30 days

    **Hemoglobin levels not required if the requested agent is being prescribed to reduce the possibility of allogenic blood transfusion in a surgery patient and there is documentation of intended high-risk surgery (must be elective, non-cardiac, and non-vascular)

3. Iron stores adequate (ferritin >100 ng/mL or transferrin saturation > 20%)

4. For ARANESP and EPOGEN, member must have tried and failed PROCRIT.

Authorization for continued use shall be reviewed at least every 3 months.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed: 11/2016

Brand Name	Generic Name
AVODART	dutasteride

CRITERIA FOR COVERAGE/NON-COVERAGE

AVODART/dutasteride will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The member has the following diagnosis:
  - Benign prostatic hyperplasia: As monotherapy or in combination with tamsulosin for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery

AND

- Member must try and fail finasteride in combination with tamsulosin

AND

- May be administered in combination with tamsulosin 0.4 mg once daily

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed: 11/2016

Brand Name	Generic Name
AZOPT	brinzolamide

CRITERIA FOR COVERAGE/NON-COVERAGE

AZOPT/brinzolamide will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The member has one of the following diagnoses:
  - Elevated intraocular pressure (IOP): Treatment of elevated IOP in patients with ocular hypertension or open-angle glaucoma

AND

- Member must try and fail two formulary medications such as betaxolol, brimonidine, carteolol, dorzolamide, latanoprost, travoprost, levobunolol, or timolol

AND

- May be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last updated: 11/2016

Covered Product	Reference Brand
BARACLUDE/entecavir	Baraclude

CRITERIA FOR COVERAGE/NONCOVERAGE

BARACLUDE® (entecavir) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member is 2 years of age or older

2. Member has a diagnosis of chronic hepatitis B

3. Member is HBsAg-positive for at least 6 months

4. Documentation of member's serum HBV DNA
    a. For HBeAg-positive patients, serum HBV DNA > 20,000 IU/mL (105 copies/mL)
    b. For HBeAg negative patients, serum HBV DNA > 2,000 IU/mL (104 copies/mL)

5. Member has evidence of persistent elevations in serum aminotransferases (alanine transaminase [ALT] or aspartate aminotransferase [AST]) at least 2 times the upper limit of normal
    *** This does not apply if member has histologically active disease (i.e. necroinflammation on biopsy)

6. If member has HIV co-infection, member must be receiving anti-retroviral therapy for treatment of HIV

BARACLUDE is subject to a quantity limit of 30 tablets per 30 days or 630 mL per 30 days (available as 210 mL in a 260 mL bottle)

Authorization for continued use shall be reviewed after 12 months to confirm the following:

- HBeAg negative patients have not had HBsAg clearance. Continued approval x 12 months
- HBeAg positive patients, detectable HBV DNA and have not been anti-Hbe for at least 6 months. Continued approval x 12 months

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed: 11/2016

Brand Name	Generic Name
BYETTA PEN	exenatide
BYDUREON PEN/VIALS	exenatide
VICTOZA PEN	liraglutide
SYMLIN PEN	pramlintide acetate

CRITERIA FOR COVERAGE/NONCOVERAGE

BYETTA, BYDUREON, SYMLIN or VICTOZA will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a diagnosis of Type 2 Diabetes Mellitus.

2. The provider has submitted documentation confirming the member's Hbg A1C level > 7% within the past 90 days.

3. Failure to obtain adequate control on metformin, a sulfonylurea or a combination of metformin and sulfonylurea, unless the patient is not a candidate for above therapy. Documentation mus include reasons why the member is not a candidate for therapy,

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last updated 03/2017

Covered Product	Reference Brand Name
celecoxib	CELEBREX

CRITERIA FOR COVERAGE/NONCOVERAGE

CELEBREX/celecoxib will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member must meet both (1) and (2) below:

1. Member meets one of the following criteria:
    a. Member is > 65 years of age
    b. Member has failed previous treatment or has an intolerance to at least two therapies with NSAIDs or salicylates
    c. Member is currently receiving treatment with any of the following drug therapy:
        i. Anticoagulants/antiplatelet agents (i.e., warfarin, heparin, LMW heparin, Pradaxa, Plavix, etc.)
        ii. Antiulcer agents (i.e. proton-pump inhibitors [PPIs], histamine-2-receptor antagonists [H2RAs], or misoprostol)
        iii. Chronic use of oral corticosteroids
        iv. Use of methotrexate
    d. Patient has a history of peptic ulcer disease or history of a GI bleed

Authorization for continued use shall be reviewed at least every 12 months to confirm that current coverage policy criteria are met, with the exception of NSAID/salicylate trial requirement, and that the patient has experienced an objective response to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

Brand Name	Generic Name
COSOPT	Dorzolamide/timolol

CRITERIA FOR COVERAGE/NONCOVERAGE

COSOPT (dorzolamide/timolol) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has been clinically diagnosed with one of the following disease states:
    a. Open-angle glaucoma in patients who are insufficiently responsive to beta-blockers
    b. Ocular hypertension in patients who are insufficiently responsive to beta-blockers
2. The member has tried and failed two formulary medications such as betaxolol, brimonidine, carteolol, dorzolamide, latanoprost, travoprost, levobunolol, or timolol

**COSOPT (dorzolamide/timolol) may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
DDAVP	Desmopressin nasal

CRITERIA FOR COVERAGE/NONCOVERAGE

DDAVP /desmopressin nasal will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Used for the treatment of Central diabetes insipidus as antidiuretic replacement therapy in the management of central cranial diabetes insipidus and for the management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.

1. Dose is consistent with FDA labeling for specific patient population
    a. Adults: Usual dosage: 10 to 40 mcg daily, either as a single dose or divided into 2 or 3 doses. Most adults require 20 mcg daily in 2 divided doses. Dosage adjustment: The morning and evening doses should be adjusted separately for an adequate diurnal rhythm of water turnover.
    b. Children 13 years and older: Usual dosage: 10 to 40 mcg daily, either as a single dose or divided into 2 or 3 doses. Dosage adjustment: The morning and evening doses should be adjusted separately for an adequate diurnal rhythm of water turnover.
    c. Children 3 months to 12 years of age: 5 to 30 mcg daily, either as a single dose or divided into 2 doses. About one-fourth to one-third of patients can be controlled by a single daily dose of desmopressin
    d. Children younger than 3 months: Safety and efficacy not established

Authorization is for 12 months

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

Covered Product	Reference Brand Name
Diclofenac 1% Gel	VOLTAREN 1% Gel

CRITERIA FOR COVERAGE/NONCOVERAGE

Diclofenac topical gel is FDA approved as a nonsteroidal anti-inflammatory drug (NSAID) for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. The total dose should not exceed 32 g per day. Per the FDA label it was not evaluated for use on joints of the spine, hip, or shoulder.

Diclofenac 1% topical gel will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has been diagnosed with pain associated with osteoarthritis of joints receptive to topical treatment, such as the knees, ankles, feet, hands, elbows, and wrists.

2. Member meets **one** of the following criteria below:
   a. Member has tried and failed an adequate course of therapy with at least **two** oral generic prescription formulary NSAID agents in the past 180 days.
   Trial defined as a 30 day trial. Failure is defined as **one** of the following:
      1. Documentation of inadequate pain relief.
      2. Documentation of harmful or intolerable gastrointestinal side effects or adverse events following the use of either meloxicam, nabumetone, or etodolac (see note below).

   Formulary NSAIDs include: ibuprofen, naproxen, naproxen DR, piroxicam, diclofenac, meloxicam, nabumetone, oxaprozin, indomethacin, indomethacin ER, flurbiprofen, fenoprofen, and etodolac.

   Note: *Meloxicam, nabumetone, and etodolac are partially selective COX-2 inhibitors at lower doses and some evidence supports they exhibit better gastrointestinal tolerance at lower doses.*

   b. Member has a documented contraindication to oral NSAID therapy such as a history of gastric or duodenal ulcers, concomitant anticoagulant or antiplatelet therapy, including warfarin and aspirin.

3. Member will not be using topical diclofenac gel concurrently with any oral NSAID (including COX-2 inhibitors like celecoxib) for the same condition.
   Note: Concomitant use has not been evaluated and may increase adverse NSAID effects. Up to 6% of the systemic levels of a single oral dose of diclofenac can be achieved with topical diclofenac administration.

Approval length: 12 months.

Continuation criteria: Authorization for continued use shall be reviewed at least every 12 months to confirm documentation of the absence of contraindications and the presence of a clinical response to therapy.

References:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 7/2017
2. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 7/2017
3. G Dammann, H. (1999). Preferential COX-2 inhibition: its clinical relevance for gastrointestinal non-steroidal anti-inflammatory rheumatic drug toxicity. *Zeitschrift für Gastroenterologie*. 37. 45-58.
4. Voltaren Gel prescribing information. Parsippany, NJ. Novartis Consumer Health, Inc. Rev Jul 2009.

Criteria reviewed: 7/2017
Criteria revised: 9/2017

Brand Name	Generic Name
DIFICID	fidaxomicin

CRITERIA FOR COVERAGE/NONCOVERAGE

DIFICID /fidaxomicin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

- For treatment of C. difficile–associated diarrhea (CDAD).

AND

- Member over 18 years old

AND

- Member must have tried and failed vancomycin.

AND

- Prescribed by a HC contracted Infectious Disease provider.

Approval Time Period: 10 days

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered products	Brand or generic Name
Donepezil tablets 5, 10 mg	ARICEPT
Donepezil orally disintegrating tablets 5, 10 mg	ARICEPT ODT
Donepezil tablets 23 mg	ARICEPT

CRITERIA FOR COVERAGE/NONCOVERAGE

Donepezil and **donepezil ODT** are acetylcholinesterase inhibitors indicated for the treatment of dementia of the Alzheimer's type. Efficacy has been demonstrated in patients with mild, moderate, and severe Alzheimer's disease. A dose of 10 mg once daily can be administered once patients have been on a daily dose of 5 mg for 4 to 6 weeks. A dose of 23 mg once daily can be administered to patients with moderate to severe disease once they have been on a dose of 10 mg once daily for at least 3 months.

Donepezil tablets and ODT in the 5 mg and 10 mg strengths will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member must be 18 years old or older.

2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.

3. Documented diagnosis of mild, moderate, or severe dementia associated with Alzheimer's disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
    a. Between 21 - 24 points for mild disease.
    b. Between 13 - 20 points for moderate disease.
    c. Less than 12 points for severe disease.

Donepezil 23 mg tablets will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. All of the above criteria has been met and the member has moderate to severe disease as defined by an MMSE score of 20 or less.

2. The member has recent documented prescription claim history of donepezil tablets or ODT 5 mg or 10 mg for three consecutive months.

Quantity Limits: #30 per 30 days

Length of Approval: Three months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

Continuation Criteria:
1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score.

Exclusions:
1. Not for use for non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.
2. Use of doses greater than 23mg per day.

References:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 9/9/17.
3. Aricept prescribing information. Woodcliff Lake, NJ. Eisai Inc. Rev Feb 2016.
4. Doody RS, Stevens JC, et al. Practice parameter: Management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology.* May 2001;Vol 56;no 9;1154-1166.
5. Folstein MF, Folstein SE, et al. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res.* 1975;12:189-198. www.dementiatoday.com/wp-content/uploads/2012/06/MiniMentalStateExamination.pdf.

Criteria created 9/2017

Brand Name	Generic Name
ELIDEL 1% CREAM	pimecrolimus

CRITERIA FOR COVERAGE/NONCOVERAGE

Elidel 1% Cream will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Member has been diagnosed with:
  - Atopic Dermatitis (eczema)
  - Vulvar Lichen Sclerosus
  - Psoriasis

AND

- Member has tried and failed an adequate course of therapy with at least two generic prescription formulary topical steroids and generic topical tacrolimus in the past 180 days unless contraindicated.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
ENBREL – Preferred Product	etanercept

CRITERIA FOR COVERAGE/NONCOVERAGE

ENBREL/etanercept will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. **Adults diagnosed with rheumatoid arthritis who meet (a) or (b) below:**
    a. Approve if the member has tried one DMARD (brand or generic; oral or injectable) for at least 2 months, [this includes members who have tried other biologic DMARDs for at least 2 months]
    b. Member is concurrently receiving MTX

    Etanercept is FDA-approved for moderate or severe active RA in adults and can be used alone or in combination with MTX.

2. **Adults diagnosed with Plaque psoriasis who meet both (a) and (b) below):**
    a. Member has minimum body surface area (BSA) involvement with plaque psoriasis of ≥ 5%. Exceptions can be made to the requirement for ≥ 5% BSA involvement in the following instances (i) or (ii):
        i. Members with plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia are not required to have a minimum BSA involvement and are not required to meet 2b below.
        ii. Members who meet all three of the following conditions are not required to have a minimum BSA involvement:
            - Member has had an inadequate response to a 3-month trial of either topical therapy, localized phototherapy with ultraviolet B (UVB), or oral methoxsalen plus UVA light (PUVA)
            - Member has had an inadequate response to a 3-month trial of systemic therapy (See 2b below for list) or has contraindications to all of these
            - Member has significant disability or impairment in physical or mental functioning, according to the treatingphysician.

    b. Member has tried a systemic therapy or phototherapy for 3 months with one of the following agents: MTX, cyclosporine, acitretin (Soriatane), adalimumab (Humira), alefacept (Amevive), infliximab (Remicade), or ustekinumab (Stelara), or has tried phototherapy with UVB or PUVA for psoriasis.

3. **Juvenile idiopathic arthritis (JIA) [or JRA], polyarticular course (regardless of type of onset).**
    a. Approve if the member has tried MTX or will be starting on etanercept concurrently with MTX.

    b. Approve without trying MTX if the member has an absolute contraindication to MTX (e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias).

    Etanercept is FDA-approved for moderately to severely active polyarticular JIA in members ages 2 and older.

4. **Adults diagnosed with Psoriatic arthritis (PsA).** Etanercept is FDA-approved for PsA and can be used in combination with MTX in members who do not respond adequately to MTX alone. In clinical trials, etanercept was effective in members with active PsA despite therapy with an NSAID.

5. **Etanercept is FDA-approved for adults diagnosed with ankylosing spondylitis.**

Approval is for 1 year. Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

QUANTITY LIMIT GUIDELINES

Dose per kit	Metric qty	Drug Name & Strength	Qty allowed for Rheumatoid Arthritis	Qty allowed for Plaque Psoriasis	Qty allowed for Psoriatic Arthritis	Qty allowed ankylosing spondylitis
4	3.92	Enbrel 50mg/ml Sureclick 3.92 Pen	4 per 28 days	8 per 28 days x 3 months; 4 per 28 days after	4 per 28 days	4 per 28 days
4	3.92	Enbrel Inj 50mg/ml PFS 3.92	4 per 28 days	8 per 28 days x 3 months; 4 per 28 days after	4 per 28 days	4 per 28 days
4	4	Enbrel Inj 25mg/ Kit 4	8 per 28 days	16 per 28 day x 3 months; 8 per 28 days after	8 per 28 days	8 per 28 days
4	2.04	Enbrel Inj 25mg/0.5ml PFS 2.04ml	8 per 28 days	16 per 28 day x 3 months; 8 per 28 days after	8 per 28 days	8 per 28 days
		Misc information	No starter tx		No starter tx	No starter tx

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

Brand Name	Generic Name
ENTRESTO	sacubitril/valsartan

CRITERIA FOR COVERAGE/NON-COVERAGE

Entresto is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker, indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

Entresto will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The initial prescription has been written by a cardiologist. Refills may be written by the primary care provider.
2. Member has a documented diagnosis of chronic heart failure NYHA class II to IV.
3. Documented reduced ejection fraction (EF) of less than or equal to 35%.
4. Member will not be taking a concomitant ACE inhibitor, ARB or aliskiren.
5. Member does not have a history of angioedema with previous ACE inhibitor or ARB therapy.
6. Member will be receiving concomitant therapy with one of the following beta-blockers at a maximally tolerated dose (unless contraindicated): bisoprolol, carvedilol or metoprolol succinate.
7. The member must have had a trial of an ACE inhibitor or ARB for at least 4 weeks.

Approvable quantity: Up to 60 tablets per 30 days.

Approval length: 12 months.

Continuation criteria: Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy and there is a documented clinical response.

References:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 08/2017.
2. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 08/2017.
3. Yancy CW, Jessup M, et al. 2016 ACC/AHA/HFS A Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation*. 2016; 134:e282-e293
4. Entresto prescribing information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Rev 8/2015.
5. McMurray JJV, Packer M, Desai AS, et al. Baseline characteristics and treatment of patients in Prospective comparison of ARNI with ACEI to Determine Impact on Global Mortality and morbidity in Heart Failure trial (PARADIGM-HF). *Eur J Heart Fail*. 2014;16(7):817-825.

Criteria revised: 9/2017

Brand Name	Generic Name
ESBRIET	pirfenidone

CRITERIA FOR COVERAGE/NONCOVERAGE

Esbriet (pirfenidone) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has

- Diagnosis of idiopathic pulmonary fibrosis;

AND

- Prescriber must be a pulmonologist;

AND

- Monitoring liver function (LFT's)

AND

- Dosing consistent with guidelines

  The recommended daily maintenance dosage of ESBRIET is 801 mg (three 267 mg capsules) three times a day with food for a total of 2403 mg/day. Doses should be taken at the same time each day.

  Upon initiation of treatment, titrate to the full dosage of nine capsules per day over a 14-day period as follows:

Dosage Titration for ESBRIET in Patients with IPF	
Treatment days	**Dosage**
Days 1 through 7	1 capsule three times a day with food
Days 8 through 14	2 capsules three times a day with food
Days 15 onward	3 capsules three times a day with food

  Dosages above 2403 mg/day (9 capsules per day) are not recommended for any patient.

Authorization will be for duration of 12 months.

Reauthorization requires documentation of response to therapy.

This guideline will be reviewed on an annual basis.

References
Esbriet [prescribing information]. Brisbane, CA: InterMune Inc.; Accessed 11/2016
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
EURAX	crotamiton

CRITERIA FOR COVERAGE/NONCOVERAGE

Eurax/crotamiton will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has the following diagnosis:

- For Adults: Eradication of scabies (Sarcoptes scabiei) and symptomatic treatment of pruritic skin.
- For children: eradication of scabies after a documented use and failure of formulary product, permethrin.

Approval duration is 1 month

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

HCA Regulatory Exclusions	
EXCLUDED DRUGS	

Certain drugs are excluded or restricted from coverage under the Pharmacy Benefit per section 1927(d)(2) of the Social Security Act. The following below is a list of those medications.

1. DESI drugs – Drugs classified as Drug Efficacy Study implementation Drugs (DESI) by the Food and Drug Administration (FDA)

2. Sexual and Erectile dysfunction drugs – Drugs prescribed solely to treat the condition of sexual dysfunction or erectile dysfunction or impotency.

3. Fertility drugs – Drugs prescribed to promote fertility are excluded.

4. Cosmetic drugs – Drugs solely for cosmetic purposes including hair growth are excluded.
   Note: Treatments indicated for psoriasis, acne, rosacea are not considered cosmetic.

5. Weight loss – Drugs prescribed for anorexia, weight loss, or weight gain are excluded.

6. Dietary supplements – Nutritional aids and medical foods are excluded.

7. Non-FDA approved drugs – Drugs that are not approved by the FDA. This includes drugs not assigned a National Drug Code (NDC).

References:

1. AHCCCS Medical Policy Manual. Policy 310-V Prescription medications/Pharmacy Services. Rev Feb 2017.
2. Arizona Administrative Code (AAC). Arizona Health Care Cost Containment System – Administration. Title 9, Chapter 22. Rev Jun 2017.
3. Social Security Act. Payment for Covered Outpatient Drugs. Title XIX §1927(d)(2).

Created 11/2017

Brand Name	Generic Name
FEMRING	estradiol vaginal ring

CRITERIA FOR COVERAGE/NONCOVERAGE

Femring / estradiol vaginal ring will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:
    a. Moderate to severe vasomotor symptoms associated with menopause
    b. Moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause.
2. There is documentation of the member's trial and failure or contraindication to two formulary estrogen products.

QL: One ring per 3 months

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
FORTEO	Teriparatide

CRITERIA FOR COVERAGE/NONCOVERAGE

FORTEO/teriparatide will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:
    a. Osteoporosis, primary or hypogonadal in men who are at high risk of fracture
    b. Osteoporosis associated with sustained systemic glucocorticoid therapy at high risk of fracture
    c. Postmenopausal osteoporosis in women who are at high risk of fracture

    **High risk of fracture is defined as a T-score that is –2.5 or lower or a history of osteoporosis-related fracture

2. The member has a documented trial and failure or contraindication to a first-line agent for osteoporosis.
    a. For females, first-line agents include oral bisphosphonates or SERM: alendronate, risedronate, ibandronate or raloxifene
    b. For males, first-line agents include oral bisphosphonates: alendronate, risedronate or ibandronate
3. The member is not receiving concomitant bisphosphonate, SERM, or Prolia (denosumab) therapy
4. Total duration of treatment with Forteo has not exceeded 2 years

Approval duration: Up to 12 months (dependent upon member's total length of therapy with Forteo)

EXCLUSIONS
Coverage of Forteo is not recommended in the following circumstances: Prevention of osteoporosis

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
FUZEON	enfuvirtide

CRITERIA FOR COVERAGE/NON-COVERAGE

FUZEON/enfuvirtide will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member must be clinically diagnosed with HIV-1 infection and meet both criteria below:

- At least 5 log (10) copies of HIV-1 RNA per ml of plasma,
- Tried/failed/intolerance to ≥ 3 classes of anti-HIV therapy (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, and protease inhibitor) after 3 or more months of therapy.

Authorization for continued use shall be reviewed at least every 3 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered products	Brand or generic Name
Galantamine oral tablets	RAZADYNE
Galantamine oral solution	RAZADYNE
Galantamine capsules controlled release (CR)	RAZADYNE ER

CRITERIA FOR COVERAGE/NONCOVERAGE

Galantamine is a cholinesterase inhibitor indicated for the treatment of mild to moderate dementia of the Alzheimer's type.
Galantamine tablets and oral solution should be administered twice a day.
Galantamine controlled released capsules should be administered once daily in the morning.

Galantamine tablets, CR capsules, or oral solution will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member must be 18 years old or older.

2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.

3. Documented diagnosis of mild to moderate dementia associated with Alzheimer's disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
   a. Between 20 – 24 points for mild disease.
   b. Between 13 – 20 points for moderate disease.

Quantity Limits:
Galantamine tablets – Up to #60 per 30 days
Galantamine oral solution – 180 ml per 30 days
Galantamine CR capsules – Up to #60 per 30 days

Length of Approval: Three months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

Continuation Criteria:
1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score.

Exclusions:
1. Not for use for non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.

References:
1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 9/9/17.
3. Razadyne prescribing information. Titusville NJ. Janssen Pharmaceuticals. Rev Sep 2016.
4. Doody RS, Stevens JC, et al. Practice parameter: Management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. May 2001;Vol 56;no 9;1154-1166.
5. Folstein MF, Folstein SE, et al. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-198. www.dementiatoday.com/wp-content/uploads/2012/06/MiniMentalStateExamination.pdf.

Criteria created 9/2017

Covered products	Brand or generic Name
GRALISE	Gabapentin extended-release tablets

CRITERIA FOR COVERAGE/NONCOVERAGE

Gralise is indicated for the management of post-herpetic neuralgia (PHN). It is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.
Gralise should be titrated up to a therapeutic dose of 1800 mg taken orally once a day. Available as a 300 mg and 600 mg tablet.

Gralise will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Documented clinical diagnosis of post-herpetic neuralgia. Post-herpetic neuralgia is defined as pain that persists more than **three** months after an individual has experienced an outbreak of herpes zoster (shingles).

2. Must be 18 years old or older.

3. Must have had a documented trial and failure or intolerance to **ALL** of the following:
    a. **Gabapentin** immediate release up to a maximum of 1,800 mg per day.
        i. Trial length defined as 90 days titrated up by 100 to 300 mg every 3 to 7 days as tolerated.
        ii. Failure defined as intolerance of severe dizziness or vertigo that is documented to impair, on a daily basis, functional living activities.
    b. **Tricyclic antidepressant** titrated up to a dose of 150 mg per day. Titration should occur every 3 to 7 days as tolerated. Trial length defined as 90 days and must consist of use of **one** of the following:
        i. Amitriptyline
        ii. Nortriptyline
        iii. Desipramine
        iv. Maprotiline
    c. **Lidocaine** topical patch up to three patches applied once per day for up to 12 hours within a 24 hour period. Patches may be cut into smaller sizes. Trial defined as 30 days.

4. Renal function is greater than a CrCL of 30 mL/min and member is not on hemodialysis.

Quantity Limits: Up to #90 per 30 days for either strength.

Length of Approval: 12 months

Continuation Criteria:
1. Documentation member is receiving a positive clinical response to Gralise based upon reevaluation in the past 12 months.

Exclusions:
1. Not for use during active outbreak of herpes zoster (shingles).
2. Gralise doses greater than 1,800 mg per day and does not exceed once daily dosing.
3. Not for use concomitantly with immediate release gabapentin due to lack of evidence and potential increase in side effects.

References:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 9/9/17.

3. Gralise prescribing information. Newark, CA. Depomed, Inc. Rev Dec 2012.
4. Dubinsky RM, Kabbani H, et al. Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* Sept 2004 vol. 63 no. 6;959-965.
5. Johnson RW, Rice A, et al. Postherpetic Neuralgia. *N Engl J Med.* 2014;371:1526-33.

Criteria created 9/2017

Criteria Name
Growth Hormone (somatropin)

Preferred products	Non-Preferred Products
GENOTROPIN	HUMATROPE
NORDITROPIN	NUTROPIN AQ NUSPIN
	OMNITROPE
	ZOMACTIN
	ZORBTIVE
	SEROSTIM

CRITERIA FOR COVERAGE/NONCOVERAGE

GROWTH HORMONE /somatropin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Preferred Products **- GENTROPIN and NORDITROPIN** are required prior to requests for non-preferred growth hormones, unless there is a documented intolerance or documented hypersensitivity to ALL preferred products. All preferred products must be considered prior to non-preferred products. An exception will be granted to the use of SEROSTIM and ZORBTIVE, when SEROSTIM or ZORBTIVE are prescribed for their FDA-approved uses.

Pediatric Uses: Children < 18 years of age: Criteria for initial authorization (12 months)

A. Member's epiphyses are open
B. Member does not have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
C. Member does not have an active malignancy
D. Member does not have active proliferative or severe non-proliferative diabetic retinopathy
E. The prescription is written by or in consultation with a pediatric endocrinologist
F. The member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:
    1. **Growth hormone deficiency (GHD)** and both the following criteria are met (i) and (ii):
        i. One pharmacological GH stimulation test result with peak GH secretion <10 ng/ml or IGF-1/IGFBP3 level more than 2 SDS below the mean if member with defined CNS pathology, history of irradiation, or proven genetic cause (acceptable tests include: arginine, clonidine, glucagon, exercise, insulin- induced hypoglycemia,levodopa)
        ii. Member meets one of the height standard deviation score or growth velocity criteria below:
            a) Height SDS more than 3 SDS below the mean for chronological age and sex
            b) Height SDS more than 2 SDS below the mean for chronological age and sex and decreased growth velocity more than 1 SDS below the mean for chronological age and sex
            c) GV measured over one year 2 SDS below the mean for chronological age and sex
    2. **Small for gestational age (SGA)** and the following criteria are met:
        i. Age is > 2 years
        ii. Child was born SGA, defined as birth weight or length two or more SDs below the mean for gestational age
        iii. Child fails to manifest catch up growth by age two years, defined as height two or more SDs below the mean for age and sex.
        iv. Request is for GENOTROPIN, NORDITROPIN, OMNITROPE, OR HUMATROPE

3. **Chronic renal insufficiency** and the following criteria are met:
    i. Child's nutritional status has been optimized and metabolic abnormalities have been corrected
    ii. Member has not had a kidney transplant
    iii. Height < 3rd percentile or a GV measured over 1 year > 2 SD below the mean for chronological age and sex.
    iv. Request is for NUTROPIN/NUTROPIN AQ

4. **Short Stature Homeobox-containing Gene (SHOX) Deficiency or Noonan Syndrome** and one of the following criteria are met:
    i. Height SDS more than 3 SDS below the mean for chronological age and sex
    ii. Height SDS more than 2 SDS below the mean for chronological age and sex and decreased growth velocity more than 1 SDS below the mean for chronological age and sex
    iii. GV measured over one year 2 SDS below the mean for chronological age and sex

    ***Request is for HUMATROPE for SHOX deficiency or NORDITROPIN for Noonan Syndrome

5. **Prader-Willi syndrome** and the following criteria are met:
    i. The diagnosis of Prader-Willi syndrome is confirmed by appropriate genetic testing
    ii. Member does not have any of the following exclusions to therapy: severe obesity, history of upper airway obstruction or sleep apnea, or severe respiratory impairment
    iii. Height SDS more than 2 SDS below the mean for chronological age and sex.
    iv. Request is for GENOTROPIN OR OMNITROPE

6. **Turner's syndrome** and the following criteria are met:
    i. The diagnosis of Turner's syndrome is confirmed by chromosome analysis
    ii. Height < 5th percentile for chronological age and sex.
    iii. Request is for HUMATROPE, GENOTROPIN, NORDITROPIN, NUTROPIN OR OMNITROPE

7. **Idiopathic short stature** and the following criteria are met:
    i. The diagnosis of ISS is confirmed by pediatric endocrinologist
    ii. Height < 2 Standard deviations (SDS) for mean chronological age and sex,
    iii. Presence of low growth velocity from mean percentile for chronological age and sex
    iv. Only 6 month trial requested
    v. Request is for OMNITROPE, GENOTROPIN, HUMATROPE OR NUTROPIN

Criteria for renewal for Pediatrics: Authorization for continued use shall be reviewed every 12 months to confirm that any of the following criteria are met:

1. Member does not have active proliferative or severe non-proliferative diabetic retinopathy
2. Member does not have an active malignancy
3. Member does not have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
4. Member is being monitored for therapy response and meet one of the following criteria:
    a. Member's epiphyses are open
    b. Final adult height has not been reached as determined by the fifth percentile of adult height
    c. GV is >2 cm/year

Growth Hormone for Adult Uses: Members ≥ 18 years of age: Criteria for initial authorization (12 months)

A. The prescription is written by or in consultation with a endocrinologist
B. Member must have completed linear growth as defined by growth rate of < 2 cm/year
C. GH treatment must be discontinued for at least one month if previously treated with somatropin for GHD in childhood
    1. Member should have a subnormal IGF-1 (after at least one month off of GH therapy in members previously receiving GH therapy)
D. Member does not have any of the following exclusions to therapy:
    1. Active proliferative or severe non-proliferative diabetic retinopathy
    2. acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
    3. Active malignancy
E. Member must have one of the following diagnoses:
    1. Childhood or adult-onset GHD confirmed or reconfirmed by subnormal response to two standard GH stimulation tests (assay type must be provided):
        i. At least one test must be the insulin tolerance test (ITT) with documented blood glucose nadir of <40 mg/dL (<2.2mmol/L); If ITT is contraindicated (which must be documented), then a standardized stimulation test (i.e. arginine plus GH releasing hormone [preferred, pending availability], glucagon,arginine)
        ii. Subnormal GH is assay dependent and defined as:

Test	*Peak GH*	*BMI*
ITT	≤5 ng/ml	N/A
Arginine	≤0.4	N/A
Glucagon	≤3 ng/ml	N/A
Arginine+ GHRH	≤11ng/m	<25 kg/m^2
	≤8 ng/ml	≥25 and <30 kg/m^2
	≤4 ng/ml	≥30 kg/m^2

    2. GHD with at least one additional pituitary hormone deficiency confirmed by a subnormal response to at least one GH stimulation test (ITT is test of choice unless contraindication, which must be documented [see above for peak GH level requirements])
    3. GHD with panhypopituitarism (three or more documented pituitary hormone deficiencies)
    4. GHD with irreversible hypothalamic-pituitary structural lesions as a result of tumors, surgery or radiation of the pituitary or hypothalamus region
F. Member must have objective evidence of complications from GHD, which can include any of the following:
    1. Low bone density as measured by BMD T-score
    2. Increased visceral fat mass measured by CT
    3. Cardiovascular complications including:
        i. Elevated blood pressure
        ii. ElevatedC-reactive protein
        iii. Low HDL, elevated LDL or total cholesterol
        iv. Increased intima-media thickness
        v. Reduced left ventricular mass or left ventricular end diastolic volume

Growth Hormone for Adult Uses: Members ≥ 18 years of age: Criteria for renewal authorization (12 months)

Authorization for continued use shall be reviewed every 12 months to confirm that any of the following criteria are met:

- Member has experienced an improvement of normalization of IGF-1 levels (not a requirement for adults with panhypopituitarism)
- Member continues to meet safety criteria

ZORBTIVE will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a diagnosis of short bowel syndrome
2. Member is receiving specialized nutritional support (i.e. parenteral nutrition)
3. Member does not have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
4. Member does not have an active malignancy
5. Member does not have active proliferative or severe non-proliferative diabetic retinopathy

**Duration of approval is limited to 4 weeks. Additional authorizations not provided.

SEROSTIM will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a diagnosis of AIDS-wasting syndrome or cachexia (defined as unintentional weight loss ≥10% of baseline weight)
2. Member has a documented trial and failure or intolerance to dronabinol or megestrol
3. Member is currently receiving treatment with antiretrovirals
4. Member does not have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
5. Member does not have an active malignancy
6. Member does not have active proliferative or severe non-proliferative diabetic retinopathy

**Initial authorization (duration limited to 12 weeks)

**Renewal authorization (duration limited to 12 weeks) and member must meet the following criteria:

- Member has experienced an increase in body weight and/or improvement in lean body mass
- Wasting is still evident
- Member continues to meet safety criteria

Serostim is considered experimental/investigational for conditions not listed in this coverage policy section.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

NON-FORMULARY HEPATITIS C DRUGS	
Brand Name	**Generic Name**
DAKLINZA	Daclatasvir
EPCLUSA	Sofosbuvir/velpatasvir
HARVONI	Ledipasvir/sofosbuvir
VIEKIRA/VIEKIRA XR	Ombitasvir/paritaprevir/ritonavir & dasabuvir
VOSEVI	Sofosbuvir/velpatasvir/voxilaprevir
ZEPATIER	Elbasvir/grazoprevir

CRITERIA FOR COVERAGE/NON-COVERAGE

Non-Formulary Hepatitis C medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.

2. Member must have a documented contraindication to a formulary hepatitis C medication or a comorbid medical condition present that a formulary hepatitis C medication is not considered clinically appropriate.
   Examples, but not all inclusive, of acceptable contraindications or medical conditions:
   - Member is stabilized on Reyataz (atazanavir)
   - Member is stabilized on Atripla (efavirenz)
   - Member is stabilized on carbamazepine for seizure disorder
   - Member is less than 18 years of age (see Appendix B for preferred approvable hepatitis C regimens for this age group)

3. The request has been submitted for an approvable Non-Formulary hepatitis C medication regimen. *Note: See Appendix A for list of the preferred non-formulary approvable Hepatitis C medications, and if all criteria is met.*

4. Member is ≥ 18 years old. *Note: See Appendix A for list of preferred approvable hepatitis C regimens for members aged 12 to 17 years old and all criteria is met.*

5. Diagnosis of chronic hepatitis C infection confirmed by documentation of **all** of the below:
   a. Detectable serum HCV RNA by quantitative assay (HCV viral load) completed within the past 90 days from the date of the prior authorization request
   b.HCV genotype
   c. Viral resistance status when applicable (e.g., NS5A resistance polymorphism testing has been submitted for a request for Zepatier for a genotype 1a member)
   d. Hepatic status (Child Pugh Score) and must include chart notes documenting if ascites and/or hepatic encephalopathy are present and cirrhosis status.

6. Documentation submitted patient readiness has been assessed and patient attestation of compliance and willingness to participate in a treatment adherence program and is on file in the member's medical record.

7. Documentation the member agrees to the following:
   a. To complete the treatment regimen.
   b. To the anticipated laboratory and imaging tests, and prescribing provider visits.
   c. Understands the risks of reinfection and other contributors to liver disease and/or damage, through a signed attestation.

8. The prescribing clinician agrees by documentation to maintain HCV RNA levels obtained at 12 & 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR).

9. Documentation the member has been screened for Hepatitis A and B and must have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity.

10. Member must be in remission for the past three months from substance abuse from the request date for treatment and must be engaged in a substance use disorder treatment program at the time of the prior authorization and over the course of the treatment if the member has/had a substance use disorder in the past 12 months.

11. Documentation the prescriber will be monitoring hemoglobin levels periodically if a member is prescribed ribavirin.

12. Ribavirin ineligibility or intolerance defined as meeting one or more of the following criteria:
    - Neutrophils <750 cells/mm3,results within the past month
    - Hemoglobin < 10g/dL, results within the past month
    - Platelets <50 000 cells/ mm3, results within the past month
    - Autoimmune hepatitis or other autoimmune condition known to be exacerbated by ribavirin

13. Prescriber has submitted the following **l**aboratory results which have been completed within the last **90 days**:
    - Total bilirubin, albumin, and INR
    - Creatinine clearance or GFR
    - LFTs
    - CBC
    - Drug/alcohol screen completed within the past 90 days.

14. **If Retreatment and** member has history of prior treatment with a direct acting antiviral (DAA), the following documentation is also required:
    a. HCV treatment history including date, drug, dosing, duration, days of therapy completed, and responses including SVRs throughout and after previous DAA therapy.
    b. Member was adherent to previous DAA therapy as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record must be provided which documents these adverse effects and recommendation of discontinuation by treatment provider.
    c. Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request for regimens that the FDA requires testing prior to treatment to ensure clinical appropriateness; and deemed medically necessary by the clinical reviewer prior to approval of the requested regimen;
    d. Member commits to the documented planned course of treatment including anticipated laboratory, imaging tests, and prescribing provider visits.

12. Hepatitis C **retreatment** will not be approved when:
    a. More than one retreatment with a DAA. Retreatment is considered an experimental service as defined in R9-22-203. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA.
    b. Documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures exists.

Exclusions:

1. DAA dosages greater than the FDA approved maximum dosage.

2. When there is documented non-adherence by a member to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures.
3. Members declining to participate in a treatment adherence program.
4. Members declining to participate in a substance abuse disorder treatment program.
5. Member life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy.
6. Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.).
7. Greater than one DAA drug regimen used for retreatment.
8. Lost or stolen medication absent of good cause.
9. Fraudulent use of HCV medications.

Approval Length: Approval length dependent on FDA approved prescribing recommendations for duration of therapy based on patient type.

APPENDIX A: Approvable hepatitis C regimens

Treatment naïve or treatment experienced with no cirrhosis or compensated cirrhosis

Approvable regimens in order of preferred status	**Treatment naive**	**Treatment experienced to interferon/ribavirin**	**Treatment experienced to PI****	**Treatment experienced to NS5A*****	**Treatment experienced to sofosbuvir**
Genotype 1	*Zepatier*	*Zepatier ± ribavirin*	*Zepatier/ribavirin*	*Vosevi*	*Vosevi*
	*Harvoni x8wks**	*Viekira XR*	*Epclusa*		
	Epclusa	*Epclusa*	*Harvoni/ribavirin*		
	Viekira	*Harvoni ± ribavirin*			
Genotype 2	*Epclusa*	*Epclusa*	*N/A*	*Vosevi*	-
Genotype 3	*Epclusa*	*Epclusa*	*N/A*	*Vosevi*	*Vosevi*
Genotype 4	*Zepatier*	*Zepatier*	*N/A*	*Vosevi*	-
	Epclusa	*Epclusa*			
	Harvoni	*Harvoni*			
Genotype 5 or 6	*Epclusa*	*Epclusa*	*N/A*	*Vosevi*	-

*****Harvoni for 8 weeks is approvable if member is treatment-naïve, genotype 1, is without cirrhosis and has a pretreatment HCV RNA less than 6 million IU/mL.

**Protease inhibitors (PI) include boceprevir, simeprevir, or telaprevir.

***NS5A inhibitors include ledipasvir, sofosbuvir, and daclatasvir.

Treatment naïve or treatment experienced with Child Pugh score of 7 or greater (Decompensated cirrhosis)

Approvable regimens in order of preferred status	**Treatment naïve or treatment experienced**
Genotype 1	*Epclusa/ribavirin*
	Harvoni/ribavirin
Genotype 2	*Epclusa/ribavirin*
Genotype 3	*Epclusa/ribavirin*
Genotype 4	*Epclusa/ribavirin*
Genotype 5 or 6	*Epclusa/ribavirin*

Liver transplant recipients

*If normal hepatic function and Metavir fibrosis score ≤ 2.

Approvable regimens in order of preferred status	**Treatment naïve or treatment experienced**
Genotype 1	*Viekira XR/ribavirin**
	Harvoni/ribavirin
Genotype 2	-
Genotype 3	*Sovaldi/Daklinza/ribavirin*
Genotype 4	*Epclusa/ribavirin*
Genotype 5 or 6	-

Pediatric members (age 12 to 17 and weigh at least 35 kg)

Approvable regimens in order of preferred status	**No cirrhosis**	**Compensated cirrhosis** (Child-Pugh < 7)	**Compensated cirrhosis** (Child-Pugh < 7) **and treatment experienced**
Genotype 1	*Harvoni x 12 weeks*	*Harvoni x 12 weeks*	*Harvoni x **24 weeks***
Genotype 4	*Harvoni x 12 weeks*	*Harvoni x 12 weeks*	*Harvoni x 12 weeks*
Genotype 5	*Harvoni x 12 weeks*	*Harvoni x 12 weeks*	*Harvoni x 12 weeks*
Genotype 6	*Harvoni x 12 weeks*	*Harvoni x 12 weeks*	*Harvoni x 12 weeks*

References:

1. FDA Safety alert. FDA Drug Safety Communication: FDA warns about the risk of hepatitis B reactivating in some patients treated with direct-acting antivirals for hepatitis C. Oct 2016.
2. Harvoni prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev Nov 2017.
3. Zepatier prescribing information. Whitehouse Station, NJ. Merck & Co., Inc. Rev Nov 2017.
4. Epclusa prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev Nov 2017.
5. Vosevi prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev Nov 2017.
6. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C.
7. Daklinza prescribing information. Princeton, NJ. Bristol-Myers Squibb Company. Rev Nov 2017.

Criteria revised 12/2017

Covered products	Brand or generic Name
HORIZANT	gabapentin enacarbil extended-release tablets

CRITERIA FOR COVERAGE/NONCOVERAGE

Horizant is indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults and the management of postherpetic neuralgia (PHN) in adults. It is not interchangeable with other gabapentin products including Gralise. Available as a 300mg and 600mg tablet.

Horizant will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Documented diagnosis of moderate-to-severe primary RLS with symptoms persisting for more than 30 days, for at least twice a week, and all of the following is met:**
    a. Must be 18 years old or older.
    b. Must have had a documented trial of 90 days in length and failure or intolerance to **ALL** of the following:
        i. **Gabapentin** immediate release titrated up every 3 to 7 days to a maximum of 1,800 mg per day. Failure is defined as intolerance of severe dizziness or vertigo that is documented to impair, on a daily basis, functional living activities.
        ii. **Pramipexole** titrated up to a maximum dose of 0.5 mg per day.
        iii. **Ropinirole** titrated up to a maximum dose of 4 mg per day.
    c. Baseline International Restless Legs Syndrome (IRLS) Rating Scale score of ≥ 15.
    d. Renal function is greater than a CrCL of 15 mL/min and member is not on hemodialysis.

2. **Documented clinical diagnosis of PHN. PHN defined as pain that persists more than three months after an individual has experienced an outbreak of herpes zoster (shingles) and all of the following is met:**
    a. Must be 18 years old or older.
    b. Must have had a documented trial and failure or intolerance to **ALL** of the following:
        i. **Gabapentin** immediate release up to 1,800 mg per day.
            1. Trial length defined as 90 days with dose titration of each of the three daily doses by 100 to 300 mg every 3 to 7 days as tolerated.
            2. Failure defined as intolerance of severe dizziness or vertigo that is documented to impair, on a daily basis, functional living activities.
        ii. **Tricyclic antidepressant** titrated up to a dose of 150 mg per day. Titration should occur every 3 to 7 days as tolerated. Trial length defined as 90 days and must consist of use of **one** of the following:
            1. Amitriptyline
            2. Nortriptyline
            3. Desipramine
            4. Maprotiline
        iii. **Lidocaine** topical patch up to three patches applied once per day for up to 12 hours within a 24 hour period. Patches may be cut into smaller sizes. Trial defined as 30 days.
    c. Renal function is greater than a CrCL of 15 mL/min and member is not on hemodialysis.

Quantity Limits:
RLS – #30 per 30 days.
PHN – Up to #60 per 30 days.

Length of Approval: 12 months

Continuation Criteria:

1. For RLS, a decrease in International Restless Legs Syndrome (IRLS) Rating Scale score from baseline.
2. For PHN, documentation member is receiving a positive clinical response to Horizant based upon reevaluation in the past 12 months.

Exclusions:

1. For PHN not for use during active outbreak of herpes zoster (shingles).
2. Horizant doses greater than 600 mg per day for RLS and greater than 1,200 mg per day for PHN and does not exceed twice daily dosing for PHN.
3. Not for use concomitantly with immediate release gabapentin due to lack of evidence and potential increase in side effects.
4. Not for use for secondary restless leg syndrome based on lack of evidence.

References:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 9/9/17.
3. Horizant prescribing information. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised 10/2016.
4. Winkelman JW, Armstrong MJ. Practice guideline summary: Treatment of restless legs syndrome in adults Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology.* Dec 2016;Vol. 87; no. 24;2585-2593.
5. Dubinsky RM, Kabbani H, et al. Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. Sep 2004 vol. 63 no. 6;959-965.
6. Johnson RW, Rice A, et al. Postherpetic Neuralgia. *N Engl J Med* 2014;371:1526-33.
7. Restless Legs Syndrome Rating Scale The International Restless Legs Syndrome Study Group. Validation of the International Restless Legs Syndrome Study Group Rating Scale for restless legs syndrome. Sleep Med 2003;4(2):121-132. www.rls.org.au/pdf/PKGD6.pdf.

Criteria created 9/2017

Brand Name Non-Formulary Drug	Generic Name
H.P. Acthar® Gel (Non-Formulary)	Repository Corticotropin Injection

CRITERIA FOR COVERAGE/NONCOVERAGE

H.P. Acthar® Gel will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Monotherapy for West Syndrome (infantile spasms) in children under 2 years of age.
   a. Must be prescribed by a neurologist or specialist in this field of study
   b. Approval duration: 2 weeks

2. Treatment of acute exacerbations of multiple sclerosis (MS) in patients age 18 years and older:
   a. Must have diagnosis of MS with evidence of acute exacerbations
   b. Must be prescribed by a neurologist or specialist in this field of study
   c. History of failure, contraindication, or intolerance to high dose corticosteroids (e.g., Solu Medrol, Depo Medrol IM) for treatment of acute MS exacerbations
   d. Approval duration: 3 weeks

3. Adjunctive therapy for short term administration for an exacerbation of psoriatic arthritis
   a. Must be prescribed by a rheumatologist or specialist in this field of study
   b. Failed or intolerant to corticosteroids
   c. Failed or intolerant to Methotrexate
   d. Failed or intolerant to Enbrel, Humira and Remicade
   e. Approval duration: 3 months

4. Adjunctive therapy for short term administration for an exacerbation of rheumatoid arthritis
   a. Must be prescribed by a rheumatologist or specialist in this field of study
   b. Failed or intolerant to at least one DMARD (e.g., sulfasalazine, hydroxychloroquine, leflunomide)
   c. Failed or intolerant to Methotrexate
   d. Failed or intolerant to Enbrel, Humira and Remicade
   e. Approval duration: 3 months

5. Adjunctive therapy for short term administration for an exacerbation of ankylosing spondylitis
   a. Must be prescribed by a rheumatologist or specialist in this field of study
   b. Failed or intolerant to an NSAID, unless contraindicated
   c. If peripheral arthritis, failed/intolerant to at least one DMARD
   d. Failed or intolerant to Enbrel, Humira and Remicade
   e. Approval duration: 3 months

6. Adjunctive therapy for short term administration for an exacerbation of juvenile rheumatoid arthritis
   a. Must be prescribed by a rheumatologist or specialist in this field of study
   b. Failed or intolerant to an NSAID, unless contraindicated and failed/intolerant to at least one DMARD
   c. Failed or intolerant to Methotrexate, Enbrel and Humira
   d. Approval duration: 3 months

7. Treatment of collagen disorders: systemic lupus erythematosus, systemic dermatomyositis
    a. Must be prescribed by a specialist in this field of study
    b. Tried or failed treatment or contraindicated with hydroxychloroquine or chloroquine
    c. Tried and failed treatment with glucocorticoids
    d. Approval duration: 3 months

8. Treatment of dermatologic disorders: Severe erytherma multiforme, Stevens-Johnson syndrome
    a. Must be prescribed by a specialist in this field of study
    b. Approval duration: 3 months

9. Treatment respiratory disease: symptomatic sarcoidosis
    a. Must be prescribed by a pulmonologist or specialist in this field of study
    b. Must have tried and failed at least 2 other standard pharmacological treatment
    c. Approval duration: 3 months

10. Treatment of edematous state: to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
    a. Must be prescribed by a nephrologist or specialist in this field of study
    b. Must have tried and failed at least 2 other standard pharmacological treatment
    c. Approval duration: 3 months

11. Treatment of ophthalmic diseases: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
    a. Must be prescribed by a specialist in this field of study
    b. Must have tried and failed at least 2 other standard pharmacological treatment
    c. Approval duration: 3 months

CONTRAINDICATIONS AND EXCLUSIONS TO COVERAGE:

- Intravenous administration
- Suspected congenital infections in infants
- Administration of live or live attenuated vaccines
- Congestive heart failure
- Uncontrolled hypertension
- Ocular herpes simplex infection
- Osteoporosis
- History or presence of peptic ulcers
- Primary adrenocortical insufficiency or adrenocortical hyperactivity
- Recent surgery
- Scleroderma
- Sensitivity to porcine protein
- Systemic fungal infection

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
HUMIRA – Preferred Product	adalimumab

CRITERIA FOR COVERAGE/NONCOVERAGE

HUMIRA / adalimumab will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. **Adults diagnosed with rheumatoid arthritis who meet (a) OR (b) below:**
    a. Member has tried one DMARD (brand or generic; oral or injectable) for at least 2 months, [this includes members who have tried other biologic DMARDs for at least 2 months]
    b. Member is concurrently receiving MTX

    Approval is for 1 year. Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

2. **Adults diagnosed with Plaque psoriasis who meet both (a) and (b) below):**
    a. Member has minimum body surface area (BSA) involvement with plaque psoriasis of ≥ 5%. Exceptions can be made to the requirement for ≥ 5% BSA involvement in the following instances (i) or (ii):
        i. Members with plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia are not required to have a minimum BSA involvement and are not required to meet 2b below.
        ii. Members who meet all three of the following conditions are not required to have a minimum BSA involvement:
            - Member has had an inadequate response to a 3-month trial of either topical therapy, localized phototherapy with ultraviolet B (UVB), or oral methoxsalen plus UVA light (PUVA)
            - Member has had an inadequate response to a 3-month trial of systemic therapy (See 2b below for list) or has contraindications to all of these
            - Member has significant disability or impairment in physical or mental functioning, according to the treating physician.
    b. Member has tried a systemic therapy or phototherapy for 3 months with one of the following agents: MTX, cyclosporine, acitretin (Soriatane), etanercept (Enbrel), alefacept (Amevive), infliximab (Remicade), or ustekinumab (Stelara), or has tried phototherapy with UVB or PUVA for psoriasis.

    Approval is for 1 year. Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

3. **For the diagnosis of Juvenile idiopathic arthritis (JIA) [or JRA], polyarticular course (regardless of type of onset), members must meet either (a) OR (b) OR (c) below:**
    a. Member has tried tried MTX, sulfasalazine, or leflunomide or a biologic DMARD (e.g., etanercept, abatacept, infliximab, anakinra), or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide
    b. Member has an absolute contraindication to MTX (e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide
    c. Member has active sacroiliac arthritis

    Approval is for 3 months.
4. **Adults diagnosed with Psoriatic arthritis (PsA):** approve for 12 months.
5. **Adults diagnosed with Hidradenitis suppurativa:** approve for 12 months.
6. **Adults diagnosed with ankylosing spondylitis:**
    a. Member must have adequate trial of at least 2 NSAIDs for pain and stiffness
    b. Member with symptomatic peripheral arthritis should have an insufficient response to at least one local corticosteroid injection, if appropriate

c. Member with persistent peripheral arthritis must have a trial of sulfasalazine
d. Member with enthesitis should try appropriate local therapy (corticosteroid injection)

Approval is for 1 year. Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

7. **Members diagnosed with moderate to severe Crohn's Disease:**
    a. Member has tried corticosteroids or if corticosteroids are contraindicated or if the patient is currently on corticosteroids (to avoid increasing the dose of the corticosteroid (Approve for 12 weeks)
    b. If the patient (adult) has received 2 doses of adalimumab to induce remission or has had 12 weeks of therapy with adalimumab (i.e., 160 mg at week 0, 80 mg at Week 2, and a maintenance dose of 40 mg EOW) and has had a response to therapy, then authorization is recommended for 12 months. Further authorization is not recommended if there is no response by Week 12. In patients who do not respond by Week 12, additional therapy does not result in significantly more responses.
    c. If the patient (adult) has not received adalimumab for induction of remission, then authorize adalimumab for maintenance (for 12 months) if the patient has tried azathioprine, 6-mercaptopurine, or MTX OR if the patient has tried infliximab (Remicade) or certolizumab (Cimzia). Patient is already in remission and adalimumab is being used to maintain remission.

8. **Adults diagnosed with ulcerative colitis**
    a. Trial and failure to immunosuppressants, such as corticosteroids, azathioprine, or 6-mercaptopurine. Approval duration is for 12 months.

9. **Adults diagnosed with intermediate, posterior uveitis or panuveitis**
    a. Member has tried ophthalmic steroids or cycloplegic mydriatics (e.g. homatropine or atropine)

QUANTITY LIMIT GUIDELINES

Doses & Metric qty	Drug Name & Strenth	Qty allowed for Rheumatoid Arthritis	Qty for Plaque Psoriasis and Uveitis	Qty allowed for Psoriatic Arthritis	Qty allowed for hidradenitis suppurativa	Qty allowed ankylosing spondylitis	Qty allowed for Crohn's/UC
6	Humira Crohns Strt Kit 40mg/0.8ml	No starter treatment	N/A	No starter treatment	One pack for new start only	No starter treatment	6 per 28 days
2	Humira Kit 40mg/0.8ml PFS 2	2 per 28 days	2 per 28 days	2 per 28 days	4 per 28 days after	2 per 28 days	2 per 28 days
2	Humira Pen 40mg/0.8ml PFP 2	2 per 28 days	2 per 28 days	2 per 28 days	NA	2 per 28 days	2 per 28 days
4	Humira Pen PS Kit 40mg/0.8ml 4	NA	New start: 4 per 28 days	NA	4 per 28 days	NA	NA
2	Humira* Kit 20mg/0.4ml PFS 2	2 per 28 days	NA	NA	NA	NA	NA
2	Humira* Kit 10mg/0.2ml PFS 2	2 per 28 days	NA	NA	NA	NA	NA

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 03/2017
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 03/2017
Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; September 2016 Accessed 03/2017
Criteria last updated: 03/2017

Brand Name- AHCCCS Preferred Product	Generic Name
HUMULIN R U-500 insulin	Insulin human injection

CRITERIA FOR COVERAGE/NON-COVERAGE

Humulin R U-500 insulin is a concentrated human insulin indicated to improve glycemic control in adults and children with diabetes mellitus requiring more than 200 units of insulin per day. Its safety and efficacy when used in combination with other insulins has not been determined. Its safety and efficacy when delivered by continuous subcutaneous infusion has not been determined.

Humulin R U-500 insulin will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

5. The member has diabetes mellitus (type 1 or 2), and documentation has been submitted to support a requirement of more than 200 units of insulin per day.

6. The route of administration is by subcutaneous injection. Use by continuous subcutaneous infusion or by insulin pump is not covered.

7. If the request is for the 20 mL multi-dose U-500 vial, the member must have a concurrent prior authorization request or current prior authorization approval for U-500 insulin syringes.

   Note: BD U-500 insulin syringes are the only available syringe that has been approved by the FDA for use with U-500 insulin at this time. They are available only by prescription and cannot be purchased over-the-counter.

Approvable quantity: The appropriate quantity per units prescribed should be approved for a 30 day supply in order to prevent waste from occurring. See available formulations below.
Example: 200 units per day of U-500 insulin equals 6,000 units per 30 days, so 4 x 3 mL Kwikpens should be approved.

Available formulations:
3 mL KwikPen
- Each 3 mL KwikPen contains 1,500 units of insulin.
- Once a KwikPen is opened (used), it must not be refrigerated and must be discarded after 28 days.

20 mL multiple dose vial containing 10,000 units of insulin
- Once opened (used), it must be discarded after 40 days whether it was refrigerated or stored at room temperature.

Approval length: 12 months.

Continuation criteria: The member must have been adherent to monthly refill quantities consistent with the number of units prescribed per day.

References:

1. Humulin R U-500 Insulin prescribing information. Indiana, IN. Eli Lilly and Co. Rev Oct 2016.
2. Cefalu WT. American Diabetes Association Standards of Medical Care in Diabetes – 2017. *Diabetes Care.* Jan 2017;40(Suppl. 1):S72-S73.
3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 7/2017
4. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 7/2017

Criteria created 9/2017

Brand Name	Generic Name
INCRELEX	mecasermin

CRITERIA FOR COVERAGE/NONCOVERAGE

INCRELEX /mecasermin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by a Pediatric Endocrinologist

2. Member's age >2 and < 20 years old

3. Member does not have active or suspected neoplasia

4. Documentation of open epiphyses

5. Member has a diagnosis of severe primary insulin-like growth factor deficiency (IGFD) or members with growth hormone gene deletion who have developed neutralizing antibodies to GH as defined by all of the following:

    a. IGF-1 level that is considered "low" (< -2 standard deviations below the mean) based on the lab's reference range
    b. Lab results within 3 months of initial request,
    c. Height standard deviation score ≤ -3.0,
    d. Normal or elevated growth hormone level, (except for growth hormone (GH) deletion), based on growth hormone stimulation test with peak greater than 10 ng/mL.

6. For indications of secondary IGF-1, must have documentation that the following conditions were ruled out:
    a. Growth Hormone Deficiency
    b. Hypothyroidism
    c. Malnutrition

Criteria for authorization renewal:

1. Increase in height velocity > 2.5cm total growth in 1 yr
2. No evidence of epiphyseal closure
3. Member has not met their expected final adult height or targeted height based on min-parental height calculation or current absolute height is <= the 25th percentile (defined as 68 inches in males and 63 inches in females).

**Authorization is for 12 months

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
INTRON® A	interferon alfa-2b

CRITERIA FOR COVERAGE/NONCOVERAGE

Intron A (interferon alfa-2b injection) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member is 18 years of age or older for all indications except Type B viral hepatitis

2. Member does not have any of the following contraindications to therapy:
   A. Uncontrolled depression
   B. Solid organ transplant other than liver
   C. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon and ribavirin

3. Member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

   A. Hairy Cell Leukemia (approval duration is 6 months)

   B. Condylomata Acuminata (genital warts)
      i. Approval duration is 3 weeks
      ii. A second course may be repeated at 12 to 16 weeks

   C. AIDS-Related Kaposi's Sarcoma (approval duration is 16 weeks)

   D. Initial treatment of clinically-aggressive Follicular Lymphoma (approval duration -- 12 months)
      i. The medication will be used concurrently with anthracycline-containing combination chemotherapy.

   E. Malignant Melanoma (approval duration -- 12 months)
      i. The request for coverage is within 56 days of surgery
      ii. The member is free of disease but at high risk for systemic recurrence.

   F. Chronic hepatitis C with compensated liver disease
      i. Member is receiving combination therapy with ribavirin, unless ribavirin is
      ii. Intron-A will NOT be used as part of triple therapy with a protease inhibitor
      iii. Member has a documented clinical reason for not using peginterferon (Pegasys or PegIntron)
      iv. Approval duration up to 48 weeks

   G. Chronic hepatitis B with compensated liver disease
      i. Documentation supporting evidence of hepatitis B viral replication
      ii. Member has been serum hepatitis B surface antigen (HBsAg)-positive for at least 6 months
      iii. Member has elevated serum ALT
      iv. Member is 1 year of age or older
      v. Authorization for HBeAg-positive hepatitis B infection shall be approved for a total of 16 weeks.
      vi. Authorization for HBeAg- negative hepatitis B infection shall be approved for a total of 48 weeks.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered Product	Brand Reference
Lidocaine 5% Ointment	XYLOCAINE

CRITERIA FOR COVERAGE/NONCOVERAGE

Lidocaine 5% ointment will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The member has a documented trial and failure with Aspercreme with Lidocaine 4% pain relieving crème.

2. The product is being used as a local anesthetic to treat pain, burns or neuropathy.

3. The requested quantity does not exceed 50gm every 30 days.

Approval Duration: 12 months

References:
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 02/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 02/2017
Criteria last reviewed and updated: 02/2017

Covered Product	Reference Brand
Itraconazole/SPORANOX	SPORANOX

CRITERIA FOR COVERAGE/NONCOVERAGE

Itraconazole capsule and SPORANOX solution will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Member has an invasive, systemic fungal infection

2. Member has onychomycosis of the finger nails and has a trial and failure of terbinafine

3. Member has onychomycosis of the toe nails and has a trial and failure of terbinafine and meets either (a) or (b) below:

    a. Member is a diabetic or is immunosuppressed/immunocompromised
    b. Member is in acute pain due to the onychomycosis with signs of associated soft tissue inflammation

4. Member has a dermal fungal infection (not including onychomycosis) where topical antifungal agents are considered first line therapy and meets either (a) or (b) or (c) or (d) below:

    a. Member must have failed or is intolerant to both an OTC and Rx topical antifungal agent used for an appropriate length of time
    b. Member has an extensive infection involving areas too large to reasonably use a topical agent
    c. Member has a chronic, recalcitrant infection
    d. Member is immunocompromised

Approval duration:

- Toenail onychomycosis: 12 weeks
- Fingernail onychomycosis: 5 weeks (2 treatment pulses for 1 week separated by 3 weeks)
- All other conditions: approval duration will be dependent upon the requested duration (if appropriate)

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

Long-acting Opioids (Preferred products)	
Butrans Patches	Xtampza ER
Embeda capsules	Morphine Sulfate ER tablets
Fentanyl patches (certain strengths)	

CRITERIA FOR COVERAGE/NON-COVERAGE

The long-acting narcotic analgesics listed above will be considered for coverage under the pharmacy benefit program when the following criteria are met:

A. The member is 18 years or older with moderate to severe chronic pain requiring a continuous, around-the-clock analgesic. Chronic pain defined as pain lasting longer than 3 months outside of active cancer treatment, palliative care, and end-of-life care.

Note: *If an active oncology diagnosis exists and the prescriber is an oncologist the PA may be overridden at the pharmacy or health plan level with ICD-10 of G89.3 (neoplasm related pain) for approval.*

B. All of the following is required to be submitted as documentation by chart notes or by labs where applicable with the prior authorization request:

1. Comprehensive pain related medical exam that meets both a. and b. listed below unless documented intolerance or contraindications exist.
    a. The member has an adequate trial and failure of at least **four** non-opioid medications and will continue these medications while on chronic opioid therapy.
        i. Anticonvulsants (e.g. gapapentin, pregabalin, etc.)
        ii. Tricyclic antidepressants
        iii. SNRIs
        iv. Topical NSAIDs (e.g. diclofenac topical gel)
        v. Topical anesthetics (e.g. lidocaine)
        vi. Oral NSAIDs or COX-2 inhibitors
        vii. Oral analgesics (e.g. acetaminophen or aspirin)
        viii. Muscle relaxants
    b. The member has an adequate trial and failure of at least **three** non-pharmacologic treatments.
        i. Cognitive behavioral therapy (CBT)
        ii. Physical therapy
        iii. Interventional treatments (e.g. epidural, neuroablation, electrical stimulation, etc.)
        iv. Chiropracty
        v. Surgery (if clinically appropriate)

2. A physician pain management specialist has assessed the pain related diagnosis and a specialist consultation has occurred if the pain diagnosis is related to orthopedics, neurology, rheumatology, gastroenterology, oncology or other specialist based on the underlying disease state.[1]
   If documented a physician pain management specialist is unavailable due to barriers such as extreme patient-provider travel distance or long wait times with appointment availability then requests may be submitted by a primary care provider (PCP) until issue is resolved.

3. The member has been educated by the prescriber on both of the following:
    a. The potential side effects of using narcotic analgesics
    b. The risk for misuse, abuse and addiction related to continuing opioid therapy

4. The member has been screened for behaviors indicative of a developing substance abuse disorder including but

not limited to abuse/misuse of current prescriptions by **ALL** of the following:

a. The prescriber has reviewed the member's profile in the AZ CSPMP (Controlled Substances Prescription Monitoring Program) within the last 30 days from the date of the request and attested it is appropriate clinically. [1, 2, 3]

Note: *Oncologists prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to review the member's CSPMP profile.*

b. Documentation of a random drug screen that includes alcohol within the past 4 months from the date of the request and that it is appropriate.[1, 3]

Note: *Oncologists who are prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to conduct a UDS.*

c. Chart notes supporting the member does not display behaviors of developing an opioid use disorder as defined by DSM-5.[3, 7]

Note: *Opioid use disorder (previously classified as opioid abuse or opioid dependence) is defined in the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5), as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year.[7]*
http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf

5. A chronic pain treatment plan is submitted and includes an opioid tapering protocol. All of the following must be submitted where applicable:

a. A detailed tapering schedule over a defined period of time. A tapering protocol should consist of no less than a 10% reduction in dose per week and no more than 50% per week.

Note: *Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages.[3]*

Note*: Although the clinical evidence review did not find high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued, tapers reducing weekly dosage by 10%–50% of the original dosage have been recommended by other clinical guidelines, and a rapid taper over 2–3 weeks has been recommended in the case of a severe adverse event such as overdose. Experts noted that tapers slower than 10% per week (e.g., 10% per month) also might be appropriate and better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., for years).[3]*

Note: *Regarding duration of use, patients can experience tolerance and loss of effectiveness of opioids over time.[3]*

b. The expected outcome in the chronic pain treatment plan for the member is either no use of opioid medication or ≤ 90 MME/day use of an opioid.

Note: *Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages.[3]*

c. The treatment plan will include a statement that if tapering (if applicable) is unsuccessful then an opioid treatment program (OTP) will be considered.

Note: *Per the Code of Federal Regulations, Title 42, Sec 8 (42 CFR § 8.12) an OTP is defined as a "program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication".[8]*

Note: *For patients meeting criteria for opioid use disorder, clinicians should offer or arrange for patients to receive evidence-based treatment, usually medication-assisted treatment with buprenorphine or methadone maintenance therapy in combination with behavioral therapies*.[3]

Note: *For patients with problematic opioid use that does not meet criteria for opioid use disorder, experts noted that clinicians can offer to taper and discontinue opioids. For patients who choose to but are unable to taper, clinicians may reassess for opioid use disorder and offer opioid agonist therapy if criteria are met.[3]*

7. Coordination of care must be occurring by the prescriber if any of the following are applicable:
    a. The prescriber is not the PCP (need evidence of coordination of care w/PCP).[1]
    b. The patient is being treated by a behavioral health provider and the prescriber is not the BH provider (need evidence of coordination of care w/BH provider).[1]
    c. The patient is in a substance abuse treatment program and there is a patient signed medical release to share information between providers.

8. The member must be considered opioid-tolerant prior to approval for the following **requested** opioids and their respective strengths listed below. If the request is for any of the following strengths listed below then criteria #9 applies.
    - Any strength of Butrans patches
    - Any strength of Embeda
    - Any strength of Fentanyl patches
    - Morphine daily dose ≥ 60mg

9. If applicable, opioid tolerant defined as members who have been taking the following for one week or longer.
    a. Morphine 60 mg/day or more.
    b. Fentanyl transdermal 25 mcg/hr or more.
    c. Oral oxycodone 30 mg/day or more.
    d. Oral hydromorphone 8 mg/day or more.
    e. Oral oxymorphone 25 mg/day or more.
    f. An equianalgesic dose of another opioid.

10. A patient/provider agreement form for pain treatment with opioid medications has been signed within 30 days by the member and the provider and has been submitted.

C. Quantity Limits (QL):

- Butrans patches - #4/28 days
- Embeda capsules - #30/30 days
- Fentanyl patches - #15/30 days
- Morphine sulfate ER tablets - #90/30 days
- Xtampza ER - #60/30 days

Note: *For patients under the age of 18, prescriptions for all opioid medications (long and short acting) will be limited to a 7 day supply except in the case of cancer, other chronic disease, or traumatic injury which will be reviewed on a case-by-case basis.*
1. For diagnosis of cancer or other chronic disease, approval duration will be for six months.
2. For traumatic injury, approval duration will be for the requested duration or up to a maximum of three months.

Approval Length: 6 months.

Continuation Criteria:

1. Documentation has been submitted that member is adhering to the chronic pain treatment plan which includes ALL of the following:
    a. Adherence to all non-opioid medications and opioid medications included in chronic pain treatment plan as verified per prescription claims history.
    b. Adherence to tapering protocol if applicable.
2. The prescriber has reviewed the member's profile in the AZ CSPMP within the last 30 days from the date of the renewal request and has attested it is appropriate.
3. A random drug screen that includes alcohol within the past 4 months has been submitted and is appropriate.

4. Chart notes have been submitted supporting the member does not display behaviors of developing an opioid use disorder as defined by DSM-5.
5. Coordination of care is occurring between the appropriate providers as described in this policy.
6. There have been no violations of the patient/provider agreement form.

References:

1.AHCCCS Medical Policy Manual. Quality Management and Performance Improvement Program Chapter 900, Policy 960.
2.Arizona Opioid Prescribing Guidelines, November 2014. www.azdhs.gov/clinicians/clinical-guidelines-recommendations
3. Dowell D, Haegerich TM, et al. CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016. *MMWR Recomm Rep* 2016; 65(No.RR-1):1-49. Available at: www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
4.www.micromedexsolutions.com Accessed 8/2017.
5.http://eanswers.factsandcomparisons.com/index.aspx Accessed 8/2017.
6.http://www.azleg.gov/ars/36/02606.htm.
7. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Publishing; 2013.
8. U.S. Government Printing Office. (2006). Code of Federal Regulations. Washington, DC: GPO.

Criteria updated 03/2017
Criteria revised 9/2017

Brand Name	Generic Name
JANUVIA	sitagliptin
JANUMET / JANUMET XR	sitagliptin/metformin
TRADJENTA	linagliptin
JENTADUETO	linagliptin/metformin
KOMBIGLYZE XR	Saxagliptin/metformin
ONGLYZA	saxagliptin

CRITERIA FOR COVERAGE/NON-COVERAGE

Januvia, **Janumet**, **Janumet XR**, **Tradjenta**, **Jentadueto**, **Onglyza**, and **Kombiglyze XR** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The member has a documented diagnosis Type 2 Diabetes Mellitus.

2. The provider has submitted laboratory documentation confirming the member's current Hbg A1C level > 7% within the past 90 days.

3. Documentation of failure to obtain meet A1C goal on **two** of the following after a 90 day trial at a minimum unless the member is not a candidate for the below therapy. Documentation must be submitted and include reason(s) why the member is not a candidate for therapy.
    a. Metformin titrated up to a therapeutic dose of 2000 mg per day or maximum tolerated.
    b. Sulfonylurea up to a therapeutic dose.
    c. A combination of metformin and sulfonylurea up to a therapeutic dose.

4. Treatment plan for Januvia, Tradjenta, and Onglyza is with the continued concurrent use of metformin unless intolerance or contraindication to metformin has been established and documented.

5. Intolerance or contraindication to metformin is defined as one or more of the below:
    a. Severe renal impairment defined and documented as eGFR below 30 mL/min/1.73 m^2.
    b. Gastric intolerance defined as nausea and vomiting despite documented titration of metformin dose over a period of time and the documented use per prescription claim history of the formulary extended-release metformin preparation.
    c. Documented unstable heart failure.

Approvable quantity: Maximum dose allowed per prescribing information unless renal or hepatic impairment limits the approvable dose.

Approval length: 6 months initially then up to 12 months thereafter dependent on clinical response.

Continuation Criteria:

1. A1C level drawn at least 6 months after therapy initiated and has not increased in comparison to baseline A1C (prior to initiation of therapy) or compared to the last drawn A1C if member has already been on therapy.
2. For Januvia, Tradjenta, and Onglyza, metformin use is continued unless intolerance or contraindication to metformin was documented at start of Januvia, Tradjenta, or Onglyza therapy.

Note: Observed non-adherence per prescription claims history to diabetes medications and other drugs in the diabetes regimen will be addressed with discussions with the prescribing provider and care management interventions. If discussions and interventions are unsuccessful then denial may occur.

References:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 8/2017.
2. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 08/2017.
3. Cefalu WT. American Diabetes Association Standards of Medical Care in Diabetes – 2017. *Diabetes Care.* Jan 2017;40(Suppl. 1):S72-S73.
4. AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm 2017. *Endocr Pract.* 2017.

Criteria revised: 9/2017

Brand Name	Generic Name
JUXTAPID™	Lomitapide mesylate

CRITERIA FOR COVERAGE/NONCOVERAGE

JUXTAPID (lomitapide mesylate) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidence by one of the following:
    - Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR
    - Untreated/pre-treatment LDL >500 mg/dL with at least one of the following:
        - Cutaneous or tendonous xanthoma before age 10 years
        - History of early vascular disease (men <55 years of age, women <60 years of age) on both sides of the family if parental LDL levels are unknown
        - Elevated LDL cholesterol levels before lipid-lowering therapy consistent with heterozygous FH in both parents where LDL levels are known:
            - LDL cholesterol >250 mg/dL in a patient aged 30 or more;
            - LDL cholesterol >220 mg/dL for patients aged 20 to 29;
            - LDL cholesterol >190 mg/dL in patients under age 20;

AND

- Juxtapid will be used as adjunct to a low-fat diet and other lipid-lowering treatments

AND

- Patient does not have any of the following contraindications to therapy:
    - Pregnancy
    - Concomitant use with strong or moderate CYP3A4 inhibitors
    - Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests

AND

- Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g. atorvastatin, rosuvastatin), unless all statins are contraindicated

Juxtapid is subject to a quantity limit of 30 tablets every 30 days.

Initial authorizations will be granted for 6 months. Reauthorizations for continued use shall be reviewed yearly. Renewal criteria shall confirm the following:

- Patient has responded to therapy (i.e. decreased LDL levels) from baseline
- Patient does not have any contraindications to therapy

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
LETAIRIS®	Ambrisentan

CRITERIA FOR COVERAGE/NONCOVERAGE

LETAIRIS® (ambrisentan) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Patient has a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II or III

2. Diagnosis was confirmed by right heart catheterization

    a. If patient was unable to undergo a right heart catheterization (e.g., patient is frail, elderly, an infant, etc.), PAH was confirmed by Doppler echocardiogram

3. Female patients have been enrolled in the Letairis REMS Programs

4. LETAIRIS is prescribed within the quantity limit of 30 tablets per 30 days

5. Prescribed by or in consultation with a pulmonologist or cardiologist

**Initial authorization is for 6 months.

**Authorization for continued use shall be reviewed at least every 12 months to confirm that efficacy was achieved (i.e., improved 6MW, O2 saturation, etc.).

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 03/2017

Brand Name	Generic Name
LEUKINE	sargramostim

CRITERIA FOR COVERAGE/NONCOVERAGE

LEUKINE (sargramostim) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by, or in consultation with an oncologist or hematologist

2. Prescriber must provide clinical documentation that states medication will be used in one of the following conditions:

    a. For use in older adult patients (55 years and older) following induction chemotherapy who have a diagnosis of Acute Myelogenous Leukemia (AML) to shorten time to neutrophil recovery.

    b. For use in patients who have received an allogeneic or autologous bone marrow transplant to accelerate myeloid recovery.

    c. For use in patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed.

    d. For mobilization of peripheral blood progenitor cells or following transplantation of autologous peripheral blood progenitor cells.

Approval will be granted for duration requested not to exceed 3 months.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

Brand Name	Generic Name
LINZESS	Linaclotide

CRITERIA FOR COVERAGE/NONCOVERAGE

Linzess is a guanylate cyclase-C agonist indicated in adults for the treatment chronic idiopathic constipation and irritable bowel syndrome with constipation (IBS-C).

Linzess will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:
    a. For the treatment of chronic idiopathic constipation in adults that meets all of the following:
        1. Prescribed by or in consultation with a specialist in gastroenterology and other possible causative conditions have been appropriately treated first and documented (organic or neurologic conditions).
        2. Clinically diagnosed documented chronic idiopathic constipation, defined as less than **three** spontaneous bowel movements (SBMs) per week, on average, with **two** or more of the following symptoms of constipation for at least **six** months:
            - Very hard stools for at least a quarter of all bowel movements.
            - Sensation of incomplete evacuation following at least a quarter of all bowel movements.
            - Straining with defecation at least a quarter of the time.
    b. For the treatment of IBS-C in members 18 years and older that meets all of the following:
        1. Prescribed by or in consultation with a specialist in gastroenterology and IBS has been first appropriately treated.
        2. Clinically diagnosed documented irritable bowel syndrome, defined as abdominal pain or discomfort occurring over at least **six months** with **two** or more of the following:
            - Relieved with defecation.
            - Onset associated with a change in stool frequency.
            - Onset associated with a change in stool form.

2. Trial and failure of **all** of the following listed below. Documentation must include dates of trial and failure in the chart notes and supported by prescription claims history. Trial must consist of a minimum of 30 days.
    a. An increase in dietary fiber by food and by fiber supplements (Metamucil).
    b. One saline laxative, such as milk of magnesia or magnesium citrate.
    c. Lactulose.
    d. Polyethylene glycol (Miralax).
    e. One stimulant laxative, such as sennosides (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada. If oral is ineffective then suppositories, such as glycerin or bisacodyl, must be attempted.

    Failure defined as a documented no change in baseline symptoms as identified in the approvable diagnoses for #1 (a, b, or c).
    Intolerance does not include the products having a bad taste.

Approval length: 6 months initially then 12 months thereafter.

Continuation criteria:
1. Consistent prescription claim history. If non-adherence is observed then re-review will occur of the request to determine if criteria for chronic constipation diagnosis is still met.
2. Documentation member is receiving a positive clinical response defined as increase in SBMs per week.

References:

1. Linzess prescribing information. Cambridge, MA. Ironwood Pharmaceuticals. Rev Mar 2017.
2. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 07/2017.
3. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 07/2017.
4. Bharucha A, Pemberton, JH, et al. American Gastroenterological Association Technical Review on Constipation. *Gastroenterology* 2013;144:218-238.

Criteria reviewed: 07/2017
Criteria revised: 9/2017

Brand Name	Generic Name
LUPRON DEPOT	Leuprolide acetate
LUPRON DEPOT-PED	Leuprolide acetate
ELIGARD	Leuprolide acetate

CRITERIA FOR COVERAGE/NON-COVERAGE

Lupron-Depot (leuprolide) is a gonadotropin releasing hormone (GnRH) agonist. Leuprolide acts as a potent inhibitor of gonadotropin secretion when given continuously and in therapeutic doses. Human studies indicate that following an initial stimulation of gonadotropins, chronic stimulation with leuprolide acetate results in suppression or "downregulation" of these hormones and consequent suppression of ovarian and testicular steroidogenesis. These effects are reversible on discontinuation of drug therapy. Leuprolide acetate is not active when given orally.
Lupron Depot should be administered under the supervision of a physician for the following indications:

- For the **management of endometriosis**, including pain relief and reduction of endometriotic lesions. Lupron Depot taken with daily norethindrone acetate 5 mg is also indicated for initial management of endometriosis and for the management of recurrence of symptoms. The recommended initial treatment is no more than 6 months. Repeat treatment for endometriosis should be limited to 6 months.
- For the **preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata** (fibroids) and taken concomitantly with iron therapy. A one-month trial period of iron alone may be attempted before use with Lupron as some patients' anemia will improve with iron alone. Recommended duration of use is not for more than three months in patients with fibroids.
- For the **palliative treatment of advanced prostate cancer.**
- For the **treatment of children with central precocious puberty (CPP).**

Lupron Depot is available in the following dosage forms:

Lupron Depot:	1-month (3.75 mg, 7.5 mg)
	3-month (11.25 mg, 22.5 mg)
	4-month (30 mg)
	6-month (45 mg)
Lupron Depot-Ped:	1-month (7.5 mg, 11.25 mg, 15mg)
	3-month (11.25 mg, 15 mg)

Eligard is also a gonadotropin releasing hormone (GnRH agonist). Eligard is indicated for the palliative treatment of advanced prostate cancer and is available in the following dosage forms:

1-month (7.5 mg)
3-month (22.5 mg)
4-month (30 mg)
6-month (45 mg)

Lupron or **Eligard** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met specific to the requested diagnosis and supported by documentation:

Endometriosis

1. Prescribed by, or in consultation with a gynecologist.

2. Member is 18 years of age or older.
3. Documented diagnosis of Stage III endometriosis or greater confirmed by laparoscopy or laparotomy
4. Documented trial of at least 90 days and failure, defined as no relief of symptoms, of both of the following in the past 12 months:
    a. One oral NSAID medication unless documented contraindication.
    b. One continuous hormonal contraceptive unless documented contraindication.
    Formulary continuous hormonal contraceptives: Medroxyprogesterone acetate IM injection, Ashlyna, Amethia, Amethia Lo, Camrese, Camrese Lo, Daysee, Introvale, Jolessa, Setlakin, and Quasense.
5. Documented trial and failure, defined as no relief of symptoms, of **one** of the following:
    a. Danazol
    b. Letrozole
    c. Levonorgestrel IUD
6. Member has not used Lupron for the treatment of endometriosis previously for a treatment course greater than 6 months in total duration.
    Note: The initial treatment course is to consist of 6 months taken consecutively. If the request is for treatment after an initial 6 month course has occurred then retreatment criteria in this policy will apply.
7. Request is for only one of the Lupron strengths listed below.
    Note: Each Lupron product listed below cannot be combined for additive strength.
    - Lupron Depot 3.75 mg, for 1-month administration
    - Lupron Depot 11.25 mg, for 3-month administration

Anemia caused by uterine leiomyoma (fibroids)

1. Prescribed by, or in consultation with a gynecologist.
2. Member is 18 years of age or older.
3. Documentation submitted to support the intent of use is to improve anemia and/or reduce uterine size for three to six months prior to a planned surgical intervention.
4. Documentation submitted to support a. and b. listed below in entirety.
    a. Anemia caused by uterine leiomyomata (fibroids).
        i. Lab report submitted of a hemoglobin level drawn within last 30 days that supports a hemoglobin level at or below reference lab values.
        ii. Member displays at least two clinical symptoms of anemia such as fatigue, shortness of breath, dizziness, headache, coldness in hands and feet, pale skin, and chest pain.
        iii. Per the treatment plan Lupron will be used concomitantly with iron therapy either by oral or intravenous routes.
    b. Uterine fibroids documented by a current ultrasound.
        i. Surgery is scheduled two to six months from date of request.
        ii. Negative pregnancy test within last 30 days.
5. Request is for only one of the Lupron strengths listed below.
    Note: Each Lupron product listed below cannot be combined for additive strength.
    - Lupron Depot 3.75 mg, for 1-month administration
    - Lupron Depot 11.25 mg, for 3-month administration

Central precocious puberty (CPP) for females

1. Prescribed by, or in consultation with a pediatric endocrinologist.
2. Documentation has been submitted supporting the onset of secondary sexual characteristics earlier than **8 years of age**.
3. Member is **less than or is 12 years of age.**
4. A diagnosis of CPP confirmed by submitted lab of an elevated basal luteinizing hormone (LH) level > 0.3 mIU/L.

5. Documentation has been submitted supporting bone age is advanced one year beyond the chronological age.
6. Baseline height and weight are submitted. *Note: Current weight required due to weight based dosing of the drug and height to measure response of drug.*
7. Documentation submitted supporting **all** of the following have been performed:
    a. Human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor
    b. Adrenal steroid measurements to exclude congenital adrenal hyperplasia
    c. Diagnostic imaging of the brain to rule out intracranial tumor(s)
    d. Pelvic and adrenal ultrasounds to rule out steroid secreting tumors
8. Request is for only one of the Lupron strengths listed below.
   Note: Each Lupron product listed below cannot be combined for additive strength
    - Lupron Depot-Ped 7.5 mg, for 1-month administration
    - Lupron Depot-Ped 11.25 mg, for 1-month administration
    - Lupron Depot-Ped 15 mg, for 1-month administration
    - Lupron Depot-Ped 11.25 mg, for 3-month administration
    - Lupron Depot-Ped 30 mg, for 3-month administration

Central precocious puberty (CPP) for males

1. Prescribed by, or in consultation with a pediatric endocrinologist.
2. Documentation has been submitted supporting the onset of secondary sexual characteristics earlier than **9 years of age.**
3. Member is **less than or is 13 years of age.**
4. A diagnosis of CPP confirmed by submitted lab of an elevated basal luteinizing hormone (LH) level > 0.3 mIU/L.
5. Documentation has been submitted supporting bone age is advanced one year beyond the chronological age.
6. Baseline height, weight, and LH levels submitted. Current weight is required due to weight based dosing and is consistent with the requested strength.
7. Documentation submitted supporting **all** of the following have been performed:
    a. Human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor.
    b. Adrenal steroid measurements to exclude congenital adrenal hyperplasia.
    c. Diagnostic imaging of the brain to rule out intracranial tumor(s).
    d. Testicular and adrenal ultrasounds to rule out steroid secreting tumors.
8. Request is for only one of the Lupron strengths listed below.
   Note: Each Lupron product listed below cannot be combined for additive strength.
    - Lupron Depot-Ped 7.5 mg, for 1-month administration
    - Lupron Depot-Ped 11.25 mg, for 1-month administration
    - Lupron Depot-Ped 15 mg, for 1-month administration
    - Lupron Depot-Ped 11.25 mg for 3-month administration
    - Lupron Depot-Ped 30 mg for 3-month administration

Palliative treatment of advanced prostate cancer

1. Prescribed by, or in consultation with an oncologist or urologist.
2. Member is 18 years of age or older.
3. Member has a diagnosis of advanced prostate cancer.
   Note: Advanced prostate cancer is defined as cancer that has spread outside of the prostate gland, such as but not limited to, into adjacent tissues, lymph nodes, or bone.
4. Request is for only one of the Lupron or Eligard strengths listed below.
   Note: Each product listed below cannot be combined for additive strength.
    - Lupron 7.5 mg, for 1-month administration
    - Lupron 22.5 mg, for 3-month administration
    - Lupron 30 mg, for 4-month administration
    - Lupron 45 mg, for 6-month administration

- Eligard 7.5 mg, for 1-month administration
- Eligard 22.5 mg, for 3-month administration
- Eligard 30 mg, for 4-month administration
- Eligard 45 mg, for 6-month administration

Gender Dysphoria disorder in adolescents

1. Documentation submitted from a pediatric endocrinologist or other clinician experienced in pubertal assessment that supports all of the following:
   a. Agreement with the indication for GnRH agonist treatment.
   b. Has confirmed puberty has started in the adolescent (Tanner stage ≥ G2/B2).
   c. Has confirmed that there are no medical contraindications to GnRH agonist treatment.

Other diagnoses

1. Requested off-label diagnosis and dosing are supported for use by one of the following compendia:
   i. American Hospital Formulary Service (AHFS) Compendium.
   ii. Micromedex/DrugDex Compendium with a ***Class I, IIa, or IIb rating.***
   iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a ***strong recommendation.***
   iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and a Strong recommendation.***
   v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) ***Category of 1, 2A, or 2B.***
2. If the above listed compendia do not support the use of the requested diagnosis then **two** published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug and dosing consistent with the diagnosis can be submitted for review.
   The clinical trials must be consistent with the drug requested including the dosing and the conclusion by the trial authors must include it is considered safe and effective for the requested use.

Approval Length:

1. *Endometriosis* – Six months for first treatment course. Six months for the retreatment course. Treatment duration for longer than twelve months is not clinically supported by evidence at this time and is considered experimental.
2. *Uterine Leiomyoma (fibroids)* – Three months initially, reapproval may occur for another three months based on clinical necessity only if anemia status and/or surgical status is submitted.
3. *Central Precocious Puberty for females and males* – Three months initially, reapproval may occur up to twelve months if continuation criteria has been met.
4. *Palliative treatment of advanced prostate cancer* – Three months initially to evaluate response then up to 12 months thereafter based on clinical response.
5. *Gender dysphoria disorder in adolescents* – Twelve months.

Continuation Criteria:

1. *Endometriosis*
   a. Documentation has been submitted supporting continued treatment or retreatment for six months.
   b. Norethindrone acetate 5 mg oral tablets will be taken concurrently with Lupron Depot for the retreatment course and is submitted as a documented part of the treatment plan.
2. *Uterine Leiomyoma (fibroids)*
   a. Documentation has been submitted supporting continued treatment due to upcoming confirmed surgery date and continued anemia per labs.
3. *Precocious puberty in females*
   a. All of the following must be submitted with documentation: Decreased growth velocity, menses cessation, and arrested pubertal progression (signs of puberty have stabilized).
   b. Current weight is submitted and it is consistent with the dose requested as per the Lupron prescribing information.

4. *Precocious puberty in males*
    a. Both of the following must be submitted with documentation: Decreased growth velocity and arrested pubertal progression (signs of puberty have stabilized).
    b. Current weight is submitted and it is consistent with the dose requested as per the Lupron prescribing information.
5. *Palliative treatment of advanced prostate cancer and other oncology related diagnoses*
    a. Documentation the member is responding to treatment and no intolerable side effects are occurring.
6. *Gender Dysphoria disorder in adolescents*
    a. Documentation has been submitted supporting continued treatment is necessary.

Exclusions:

1. For the diagnosis of precocious puberty, the use of the Lupron Depot 3-month formulation is excluded if this formulation will be active systemically past the full age of 12 for females and age 13 for males. Use of the one-month formulation may be an option instead if this situation applies and if all criteria is met.
2. Use of Lupron or Lupron-Ped for peripheral precocity or benign/non-progressive pubertal variants.

References:

1. Lupron Depot prescribing information. North Chicago, IL. Abbvie Inc. Rev May 2017.
2. Lupron Depot-Ped prescribing information. North Chicago, IL. Abbvie Inc. Rev May 2017.
3. Practice Committee of the American Society for Reproductive Medicine. Treatment of pelvic pain associated with endometriosis: A committee opinion. *Fertil Steril.* 2014 Apr;101(4):927-35.
4. Kaplowitz PB, Bloch CA. Evaluation and Referral of Children with Signs of Early Puberty. *Pediatrics*. Jan 2016 Vol 137(1).
5. Micromedex/DrugDex System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA.
6. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017.
7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
8. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&.
9. Selak V, Farquhar C, et al. Danazol for pelvic pain associated with endometriosis. *Cochrane Database Syst Rev. 2007.*
10. Nawathe A, Patwardhan S, et al. Systematic review of the effects of aromatase inhibitors on pain associated with endometriosis. *BJOG.* 2008 Jun;115(7):818-22.
11. Walch K, Unfried G, et al. Implanon versus medroxyprogesterone acetate: Effects on pain scores in patient with symptomatic endometriosis – a pilot study. *Contraception.* 2009;79)1):29.
12. Yisa SB, Okenwa AA, et al. Treatment of pelvic endometriosis with etonogestrel subdermal implant (Implanon). *J Fam Plann Reprod Health Care*. 2005;31(1):67.
13. Hembree WC, Cohen-Kettenis PT, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. Nov 2017, 102(11):3869-3903.
14. Eligard prescribing information. Fort Collins, CO. Tolmar Pharmaceuticals Inc. Rev Jul 2016.

Criteria created 10/2017

Brand Name	Generic Name
LYRICA	Pregabalin

CRITERIA FOR COVERAGE/NONCOVERAGE

LYRICA (pregabalin) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Partial-onset seizures: as adjunctive therapy of partial-onset seizures in patients 18 years of age and older.
    a. Member has tried and failed at least 2 generically available anticonvulsants

2. Fibromyalgia
    a. Member has tried and failed duloxetine (generic Cymbalta)

3. Neuropathic pain associated with diabetic peripheral neuropathy
    a. Member has tried and failed gabapentin (generic Neurontin)

4. Neuropathic pain associated with spinal cord injury
    a. Member has tried and failed gabapentin (generic Neurontin)

5. Postherpetic neuralgia
    a. Member has tried and failed gabapentin (generic Neurontin)

Quantity Level Limits:

- For the following strengths: 25mg/50mg75mg/100mg/150mg/200mg, QL is #90 every 30 days
- For the following strengths: 225mg/300mg, QL is #60 every 30 days

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts& ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
MAKENA	hydroxyprogesterone caproate injection

CRITERIA FOR COVERAGE/NONCOVERAGE

MAKENA will be considered for coverage under the pharmacy benefit program when indicated use is to reduce the risk of preterm birth AND the following criteria are met:

- Patient is currently pregnant with singleton gestation
- Patient has a history of a spontaneous preterm singleton delivery (i.e. delivery of an infant < 37 weeks gestation)
- Prescribed by, or in consultation with, a provider of obstetrical care
- The indicated usage must be supported by documentation from the patient's medical records

Use of Makena is not recommended in the following circumstances:

- Current or history of thrombosis or thromboembolic disorders
- Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions
- Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
- Cholestatic jaundice of pregnancy
- Liver tumors, benign or malignant, or active liver disease
- Uncontrolled hypertension
- Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth

Duration of therapy:

- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation
- Continue administration of 250mg intramuscularly once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 10/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 10/2016
Criteria last reviewed: 10/2016

HCA	
Brand Name	**Generic Name**
MAVYRET	Glecaprevir/pibrentasvir

CRITERIA FOR COVERAGE/NON-COVERAGE

Mavyret is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A).
Mavyret is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
Mavyret is available in a tablet form and the recommended dose is three tablets taken once daily with food.

Approvable Treatment Regimens and Durations:

Treatment Naïve or PRS experienced*	**Treatment Duration**	
Genotype	*No Cirrhosis*	*Compensated Cirrhosis (Child-Pugh A)*
1, 2, 3, 4, 5, or 6	8 weeks	12 weeks

*Treatment experienced to pegylated interferon, ribavirin, or sofosbuvir (PRS)

Treatment Experienced	**Previously treated with:**	**Treatment Duration**	
Genotype	*Regimen*	*No Cirrhosis*	*Compensated cirrhosis (CP-A)*
1	NS5A inhibitor without NS3/4A	16 weeks	16 weeks
1	NS3/4A PI without NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5 or 6	PRS*	8 weeks	12 weeks
3	PRS*	16 weeks	16 weeks

*Treatment experienced to pegylated interferon, ribavirin, or sofosbuvir (PRS)
NS5A inhibitors include: ledipasvir, sofosbuvir, daclatasvir
NS3/4A protease inhibitors include: simeprevir, boceprevir, telaprevir

Mavyret tablets will be considered for coverage under the pharmacy benefit program when the following criteria are met:

12. Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.

13. Member is ≥ 18 years old.
Note: For members ages 12+ please submit request for Harvoni

14. Diagnosis of chronic hepatitis C infection confirmed by documentation of **al**l of the below:
    e. Detectable serum HCV RNA by quantitative assay (HCV viral load) completed within the past 90 days from the date of the prior authorization request
    f. HCV genotype
    g. Viral resistance status (when applicable)
    h. Hepatic status (Child Pugh Score) and must include chart notes documenting if ascites and/or hepatic encephalopathy are present and cirrhosis status.

15. Documentation submitted patient readiness has been assessed and patient attestation of compliance and willingness to participate in a treatment adherence program and is on file in the member's medical record.

16. Documentation the member agrees to the following:
    d. To complete the treatment regimen.
    e. To the anticipated laboratory and imaging tests, and prescribing provider visits.
    f. Understands the risks of reinfection and other contributors to liver disease and/or damage, through a signed attestation.

17. The prescribing clinician agrees by documentation to maintain HCV RNA levels obtained at 12 & 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR).

18. Documentation the member has been screened for Hepatitis A and B and must have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity.

19. Member must be in remission for the past three months from substance abuse from the request date for treatment and must be engaged in a substance use disorder treatment program at the time of the prior authorization and over the course of the treatment if the member has/had a substance use disorder in the past 12 months. Prescribers may use the CSPMP as a tool to aid in the review of compliance.

20. Documentation the prescriber will be monitoring hemoglobin levels periodically if a member is prescribed ribavirin.

21. Prescriber has submitted the following **l**aboratory results which have been completed within the last **90 days**:
    - Total bilirubin, albumin, and INR
    - Creatinine clearance or GFR
    - LFTs
    - CBC
    - Drug/alcohol screen completed within the past 90 days.

22. **If Retreatment,** member has history of prior treatment with a direct acting antiviral (DAA), the following documentation is also required:
    e. HCV treatment history including date, drug, dosing duration and days of therapy completed and responses including SVRs throughout and after previous DAA therapy.
    f. Member was adherent to previous DAA therapy as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record must be provided which documents these adverse effects and recommendation of discontinuation by treatment provider.
    g. Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request for regimens that the FDA requires testing prior to treatment to ensure clinical appropriateness; and deemed medically necessary by the clinical reviewer prior to approval of the requested regimen;
    h. Member commits to the documented planned course of treatment including anticipated laboratory, imaging tests, and prescribing provider visits.

12. Hepatitis C **retreatment** will not be approved when:
    c. More than one retreatment with a DAA is requested. Retreatment is considered an experimental service as defined in R9-22-203. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA.
    d. Documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures exists.

Exclusions:

1. DAA dosages greater than the FDA approved maximum dosage.

2. When there is documented non-adherence by a member to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures.
3. Members declining to participate in a treatment adherence program.
4. Members declining to participate in a substance abuse disorder treatment program.
5. Member life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy.
6. Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.).
7. Greater than one DAA drug regimen used for retreatment.
8. Lost or stolen medication absent of good cause.
9. Fraudulent use of HCV medications.

Quantity Limit: Three tablets per day.

References:

1. Mavyret prescribing information. North Chicago, IL. AbbVie Inc. Rev Aug 2017
2. AHCCCS Medical Policy Manual (AMPM) Section 310-V – Covered Services.
3. AHCCCS Medical Policy Manual (AMPM) Section 320-N – Services with Special Circumstances, Hepatitis C (HCV) Prior Authorization Requirements for Direct Acting Antiviral Medication Treatment.
4. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org.

Criteria created 1/2018

Covered products	Brand or generic Name
Memantine tablets	NAMENDA
Memantine solution	NAMENDA

CRITERIA FOR COVERAGE/NONCOVERAGE

Memantine is an N-methyl-D-aspartate (NMDA) receptor antagonist indicated for the treatment of moderate to severe dementia of the Alzheimer's type.
The initial recommended dose is 5 mg once daily. Increase the dose in 5 mg increments to a maintenance dose of 10 mg twice daily. A minimum of 1 week of treatment with the previous dose should be observed before increasing the dose.

Memantine tablets and oral solution will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member must be 18 years old or older.

2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.

3. Documented diagnosis of mild, moderate, or severe dementia associated with Alzheimer's disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
    a. Between 21 – 24 points for mild disease.
    b. Between 13 – 20 points for moderate disease.
    b. Less than 12 points for severe disease.

Quantity Limits:
Memantine tablets – Up to #60 per 30 days
Memantine solution – Up to 600 mL per 30 days

Length of Approval: Three months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

Continuation Criteria:
1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score.

Exclusions:
1. Not for use for non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.

References:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 9/9/17.
3. Namenda prescribing information. Irvine, CA. Allergan USA, Inc. Rev Aug 2016.
4. Folstein MF, Folstein SE, et al. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-198. www.dementiatoday.com/wp-content/uploads/2012/06/MiniMentalStateExamination.pdf
5. Doody RS, Stevens JC, et al. Practice parameter: Management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. May 2001;Vol 56;no 9;1154-1166.

Criteria created 9/2017 **Covered Product**	**Brand Reference**
modafinil	PROVIGIL

CRITERIA FOR COVERAGE/NONCOVERAGE

Provigil (modafinil) will be considered for coverage under the pharmacy benefit program for all patients when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Diagnosis of Narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)
2. Diagnosis of Obstructive sleep apnea as defined by (a) or (b) below AND member must meet criteria (c) below:
    a. 15 or more obstructive respiratory events (apneas, hypopneas, or respiratory effort related arousals [RERA]) per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)
    b. 5 or more obstructive respiratory events (apneas, hypopneas, or respiratory effort related arousals [RERA]) per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) AND the member has one of the following symptoms
        - Unintentional sleep episodes during wakefulness
        - Daytime sleepiness
        - Unrefreshing sleep
        - Fatigue
        - Insomnia
        - Waking up breath holding, gasping, or choking
        - Loud snoring
        - Breathing interruptions during sleep
    c. Member has been fully compliant with the standard treatments for the underlying obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BPAP], etc.) that have been used for 3 months or longer
    d. For reauthorization of continued use, member continues to be fully compliant on concurrent standard treatment(s) for the underlying obstruction (e.g., CPAP, BPAP, etc.) AND member is experiencing relief of symptomatic hypersomnolence with modafinil
3. Diagnosis of Shift-work sleep disorder confirmed by (a) or (b) below:
    a. Symptoms of excessive sleepiness or insomnia, for at least 3 months, which is temporally associated with a work period (usually night work) that occurs during the habitual sleep phase
    b. Sleep study demonstrating loss of a normal sleep wake pattern (i.e., disturbed chronobiologic rhythmicity)
4. To improve wakefulness in adult patients with shift-work sleep disorder.

Authorization for continued use shall be reviewed at least every 12 months to confirm that the patient has not experienced positive response to therapy

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

MULTIPLE SCLEROSIS INJECTABLE MEDICATIONS	
Brand Name	**Generic Name**
COPAXONE (brand name only)	Glatiramer acetate
AVONEX	Interferon beta-1a
BETASERON	Interferon beta-1b
REBIF Rebidose	Interferon beta-1a
PLEGRIDY	Peginterferon beta-1a

CRITERIA FOR COVERAGE/NON-COVERAGE

Copaxone is indicated for the treatment of patients with relapsing forms of multiple sclerosis. The active ingredient is glatiramer and the mechanism by which its effect is exerted is unknown but thought to be due to modification of immune processes.

Avonex, **Rebif**, **Betaseron**, and **Plegridy** are interferon beta products indicated for the treatment of patients with relapsing forms of multiple sclerosis.

The above medications will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by, or in consultation with a neurologist or multiple sclerosis specialist.
2. Must be 18 years of age or older.
3. Documented clinical diagnosis of a relapsing form of multiple sclerosis.

Note: *There are four types of multiple sclerosis. Secondary-Progressive is considered a relapsing form if a patient is having relapses. Primary-Progressive is not a relapsing form of multiple sclerosis.*

- ***Relapsing-Remitting MS (RRMS)**. This is the most common form of multiple sclerosis. About 85% of people with MS are initially diagnosed with RRMS. People with RRMS have temporary periods called relapses, flare-ups or exacerbations, when new symptoms appear[1]*
- ***Secondary-Progressive MS (SPMS)**. In SPMS, symptoms worsen more steadily over time, with or without the occurrence of relapses and remissions. Most people who are diagnosed with RRMS will transition to SPMS at some point[2]*
- ***Primary-Progressive MS (PPMS)**. This type of MS is not very common, occurring in about 10% of people with MS. PPMS is characterized by slowly worsening symptoms from the beginning, with no relapses or remissions[1]*
- ***Progressive-Relapsing MS (PRMS)**. A rare form of MS (5%), PRMS is characterized by a steadily worsening disease state from the beginning, with acute relapses but no remissions, with or without recovery[1]*

AND each of the below criteria is met for the respective requested medication:

Copaxone

1. Request is for either Copaxone (brand name) 20 mg/mL daily or Copaxone (brand name) 40 mg/mL three times a week.

Avonex

1. Request is for Avonex to be injected once a week.
2. Baseline liver function tests are drawn and submitted supporting no serious hepatotoxicity.

Betaseron
1. Request is for Betaseron to be injected every other day.
2. Baseline liver function tests are drawn and submitted supporting no serious hepatotoxicity.

Rebif
1. Request is for Rebif to be injected three times a week.
2. Baseline liver function tests are drawn and submitted supporting no serious hepatotoxicity.

Plegridy
1. Request is for Plegridy to be injected every 14 days.
2. Baseline liver function tests are drawn and submitted supporting no serious hepatotoxicity.

Exclusions:
1. If the member has a non-relapsing form of multiple sclerosis such as primary progressive MS. The efficacy of these products in this policy has not been established in patients with MS with non-relapsing forms of MS.
2. Concurrent use with other multiple sclerosis disease-modifying agents.
   Note: An exception is the use of Ampyra (dalfampridine).

Approval length: 12 months

Continuation criteria:
1. Member has been re-evaluated in the last twelve months and documentation submitted supports disease stabilization or improvement.

References:

1. Hooper K. Managing Progressive MS. New York, NY: National Multiple Sclerosis Society 2011.
2. Multiple Sclerosis: Just the Facts New York, NY; National Multiple Sclerosis Society 2011.
3. Avonex prescribing information. Cambridge, MA. Biogen Inc. Rev Oct 2015.
4. Betaseron prescribing information. Whippany, NJ. Bayer Healthcare Pharmaceuticals. Rev Apr 2016.
5. Plegridy prescribing information. Cambridge, MA. Biogen Inc. Rev Oct 2015.
6. Copaxone prescribing information. Overland Park, MO. Teva Neuroscience Inc. Rev Aug 2016.
7. Rebif prescribing information. Rockland, MA. EMD Serono. Rev Oct 2015.
8. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, CO, USA.
9. Facts and Comparisons eAnswers [database online]. Hudson, OH. Wolters Kluwer Clinical Drug Information, Inc 2017.

Criteria revised 10/2017

MULTIPLE SCLEROSIS ORAL MEDICATIONS	
Brand Name	**Generic Name**
GILENYA	Fingolimod
TECFIDERA	Dimethyl fumarate
AUBAGIO	Teriflunomide

CRITERIA FOR COVERAGE/NON-COVERAGE

Gilenya is a sphingosine 1-phosphaste receptor modulator in an oral capsule indicated for the treatment of relapsing forms of multiple sclerosis (MS).
Tecfidera is a delayed-release oral capsule indicated for the treatment of relapsing forms of MS. The mechanism by which dimethyl fumarate exerts its therapeutic effect is unknown.
Aubagio is an oral tablet pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of MS.

The above medications will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by, or in consultation with a neurologist or multiple sclerosis specialist.
2. Must be 18 years of age or older.
3. Documented clinical diagnosis of a relapsing form of multiple sclerosis.

Note: *There are four types of multiple sclerosis. Secondary-Progressive is considered a relapsing form if a patient is having relapses. Primary-Progressive is not a relapsing form of multiple sclerosis.*

- ***Relapsing-Remitting MS (RRMS)**. This is the most common form of multiple sclerosis. About 85% of people with MS are initially diagnosed with RRMS. People with RRMS have temporary periods called relapses, flare-ups or exacerbations, when new symptoms appear[4]*
- ***Secondary-Progressive MS (SPMS)**. In SPMS, symptoms worsen more steadily over time, with or without the occurrence of relapses and remissions. Most people who are diagnosed with RRMS will transition to SPMS at some point[5]*
- ***Primary-Progressive MS (PPMS)**. This type of MS is not very common, occurring in about 10% of people with MS. PPMS is characterized by slowly worsening symptoms from the beginning, with no relapses or remissions[4]*
- ***Progressive-Relapsing MS (PRMS)**. A rare form of MS (5%), PRMS is characterized by a steadily worsening disease state from the beginning, with acute relapses but no remissions, with or without recovery[4]*

AND each of the below criteria is met for the respective requested medication:

<u>Gilenya</u>

1. Request is for one capsule to be taken once daily.
2. Baseline liver function tests are drawn and submitted supporting no serious hepatotoxicity.
3. Documentation supporting the member has not experienced in the last six months a myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure (requiring hospitalization or Class III/IV heart failure), treatment with a Class 1a or Class III anti-arrhythmic drug, or has a baseline QTc interval ≥ 500 ms.

<u>Tecfidera</u>

1. Request is for Tecfidera to be taken twice a day.
2. Baseline liver function tests are drawn and submitted supporting no serious hepatotoxicity.

Aubagio

1. Request is for one tablet to be taken once a day.
2. Baseline liver function tests are drawn and submitted supporting no serious hepatotoxicity.
3. Documentation submitted and/or prescription claim history supports all of the following is not occurring:
    - Member is a pregnant woman or woman of childbearing potential not using reliable contraception
    - Co-administration with leflunomide
    - Co-administration with rosuvastatin doses greater than 10mg

Exclusions:

1. If the member has a non-relapsing form of multiple sclerosis such as primary progressive MS. The efficacy of these products in this policy has not been established in patients with MS with non-relapsing forms of MS.
2. Concurrent use with other multiple sclerosis disease-modifying agents.
   Note: An exception is the concurrent use of Ampyra (dalfampridine).

Approval length: 12 months

Continuation criteria:

1. Member has been re-evaluated in the last twelve months and documentation submitted supports disease stabilization or improvement.

References:

1. Gilenya prescribing information. East Hanover, NJ. Novartis. Rev Feb 2016.
2. Tecfidera prescribing information. Cambridge, MA. Biogen, Inc. Rev Jan 2017.
3. Aubagio prescribing information. Cambridge, MA. Genzyme Corp. Rev Nov 2016.
4. Hooper K. Managing Progressive MS. New York, NY. National Multiple Sclerosis Society 2011.
5. Multiple Sclerosis: Just the Facts New York, NY. National Multiple Sclerosis Society 2011.
6. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, CO, USA.
7. Facts and Comparisons eAnswers [database online]. Hudson, OH. Wolters Kluwer Clinical Drug Information, Inc 2017.

Criteria revised 10/2017

Brand Name	Generic Name
MYALEPT	Metreleptin

CRITERIA FOR COVERAGE/NONCOVERAGE

MYALEPT™ (metreleptin) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a diagnosis of congenital or acquired generalized lipodystrophy

2. Documented chart notes that show member has one or more of the following metabolic abnormalities:
    a. Insulin resistance (defined as requiring more than 200 units per day)
    b. Hypertriglyceridemia
    c. Diabetes

3. Member is refractory to current standards of care for lipid and diabetic management

4. Prescribed by or in consultation with an endocrinologist

Initial Authorization: 12 months

Authorization for continued use shall be reviewed at least every 12 months when there is documentation showing the member has experienced an objective response to therapy that meets one of the criteria (a) or (b) below:

a) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline
b) Sustained reduction in triglyceride (TG) levels from baseline

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

Brand Name	Generic Name
MYTESI (formerly Fulyzaq)	crofelemer

CRITERIA FOR COVERAGE/NONCOVERAGE

MYTESI/crofelemer will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Member is at least 18 years of age

AND

- Member requires symptomatic relief of noninfectious diarrhea

AND

- Infectious diarrhea (e.g. cryptosporidiosis, c. difficile, etc.) has been ruled out

AND

- Member has HIV/AIDS and is receiving anti-retroviral therapy

AND

- Member has tried and failed at least one anti-diarrheal medication (i.e. loperamide or atropine/diphenoxylate)

MYTESI ™ (crofelemer) will be subject to the following quantity limit: 2 tablets/day.

Initial authorizations will be granted for 3 months. Reauthorizations for continued use shall be reviewed yearly. Renewal criteria shall confirm the member has had an objective response to therapy, defined as improvement in diarrhea symptoms.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
NEULASTA	pegfilgrastim

CRITERIA FOR COVERAGE/NONCOVERAGE

Neulasta / pegfilgrastim will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by, or in consultation with, an oncologist or hematologist

2. Members must be clinically diagnosed with one of the following disease states:

    A. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy.

    B. Radiation injury of bone marrow, Acute exposure of myelosuppressive radiation doses

APPROVAL DURATION: 3 Months

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
NEUPOGEN	filgrastim

CRITERIA FOR COVERAGE/NONCOVERAGE

Neupogen / filgrastim will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by, or in consultation with, an oncologist or hematologist

2. Members must be clinically diagnosed with one of the following disease states:

    A. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy.

    B. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation

    C. Prophylaxis of febrile neutropenia in patients with acute myeloid leukemia receiving chemotherapy

    D. Harvesting of peripheral blood stem cells -- for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

    E. Chronic neutropenic disorder (severe, symptomatic)

        i. Absolute neutrophil count (ANC) < 1000 cells/mm3

    F. Radiation injury of bone marrow, Acute exposure of myelosuppressive radiation doses

Approval duration: 12 months

Exclusions: Serious allergic reactions to human granulocyte colony-stimulating factors (eg, filgrastim, pegfilgrastim), or any component of the product

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed11/2016
Facts& ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 11/2016
Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen; June 2016. Accessed 11/2016
Criteria last reviewed and updated 11/2016

Brand Name	Generic Name
NEVANAC®	Nepafenac 0.1%

CRITERIA FOR COVERAGE/NONCOVERAGE

NEVANAC® (Nepafenac) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient is having cataract surgery

AND

- Patient has an inflammatory disorder of the eye defined as:
  - Increased Intraocular Pressure (defined as IOP greater than 22mmHg)

OR

  - Patients being treated for increased IOP –
    - Glaucoma Patients
    - Pre-glaucoma Patients

NEVANAC® (Nepafenac) is subject to a quantity limit of 1 bottle (2.5mls) per surgical eye.

Approval will be granted for 1 months unless shorter duration requested by prescriber.

References:
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. 11/2016
American Academy of Ophthalmology at http://www.aao.org Accessed 11/2016
Criteria last reviewed 11/2016

Brand Name	Generic Name
NORTHERA	droxidopa

CRITERIA FOR COVERAGE/NONCOVERAGE

NORTHERA™ (droxidopa) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has a diagnosis of neurogenic orthostatic hypotension (NOH)

AND

- NOH is due to one of the following:
  - primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure)
  - dopamine beta-hydroxylase deficiency
  - non-diabetic autonomic neuropathy

AND

- Patient has symptoms of NOH:
  - Orthostatic dizziness
  - Lightheadedness
  - "feeling that you are about to black out"

AND

- Patient is an adult 18 years of age or older

AND

- Patient has tried and had an inadequate response, contraindication or intolerance to midodrine and one other medication used for the management of NOH (i.e. fludrocortisone, octreotide, desmopressin)

Authorization:

Authorization will be for 3 months.
Reauthorization every 3 month requires confirmation the following:

- Patient does not have persistent or sustained supine hypertension (SBP > 180 mmHg or DBP > 110 mmHg)
- Patient does not have persistent or sustained standing or sitting hypertension (SBP > 180 mmHg or DBP > 110 mmHg)
- Patient had improvement in symptoms of NOH

**Sustained = elevated blood pressure that persists for longer than 5 minutes after change in position.
**Persistent = occurs on more than one occasion on separate MDO visits

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 11/2016
Criteria last reviewed and updated: 11/2016

NONFORMULARY	
Brand Name	**Generic Name**
BELSOMRA	suvorexant

CRITERIA FOR COVERAGE/NON-COVERAGE

Belsomra is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Belsomra will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia. Chronic insomnia is defined as difficulty initiating or maintaining sleep or early-morning awakening with inability to return to sleep and has occurred for at least 3 nights per week and is present for at least 3 months.

2. The member is over the age of 18 years old.

3. A documented trial of at least 30 days and failure of each of the following at maximum therapeutic doses:
   a.Zolpidem 10mg
   b.Temazepam 30mg
   c.Eszopiclone 3mg (prior authorization may be required)

Exclusions for coverage:
1. Documented diagnosis of narcolepsy.
2. Severe hepatic impairment defined as Child-Pugh Class C.
3. Concomitant use with other insomnia medications.
4. Concomitant use with modafinil or armodafinil.

Approvable quantity:
1. Quantities greater than #30 per 30 days will not be approved. Maximum daily dose is 20mg daily.

Continuation criteria:
1. Consistent prescription fill history verified per prescription claims of Belsomra.
2. Documentation is received the member is experiencing a positive therapeutic response.

References:

1. Belsomra prescribing information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. Rev May 2016.
2. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;12(2):307-349.

Criteria Created 9/2017

NONFORMULARY	
Brand Name	**Generic Name**
DUPIXENT	dupilumab

CRITERIA FOR COVERAGE/NON-COVERAGE

Dupixent is an interleukin-4 receptor alpha antagonist indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids. It is administered by subcutaneous injection in the form of a prefilled syringe. The recommended dose is an initial dose of 600 mg followed by 300 mg every other week.

Dupixent will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Adults with chronic moderate-to-severe atopic dermatitis (according to American Academy of Dermatology Consensus Criteria) and meets **all** of the following:
    a. Documentation of greater than or equal to 10% body surface area (BSA) of atopic dermatitis involvement.
    b. Documented baseline EASI (Eczema Area and Severity Index) score of 25.
    c. Documented baseline Pruritus NRS score ≥ 4.
    d. Documented recent history of trial and failure (within 6 months) with either inadequate response after trial of 90 days, intolerance, or contraindication to **all** of the following:
        i. Treatment with a moderate to very high potency topical corticosteroid.
        ii. Treatment with a topical calcineurin inhibitor such as Elidel or Protopic (prior authorization required).
        iii. Oral cyclosporine or methotrexate.
        iv. Localized phototherapy with ultraviolet B (UVB) or UVA light (PUVA).

2. Prescribed by, or in conjunction with a Dermatologist, Allergist, or Immunologist.

Approval Length: Initial approval for 3 months to evaluate response, further approvals may be extended to 12 months dependent on clinical response.

Continuation Criteria: Authorization for continued use shall be reviewed to confirm **all** of the following have occurred and are supported with documentation.

1. Reduction in EASI scores from baseline by 25%.
2. Significant change in pruritus defined as decrease in Pruritus NRS score by 50%.
3. Decrease in affected body area from baseline by 50%.
4. Consistent prescription fill history of Dupixent.

Approvable Quantity:

Doses per kit	Metric qty	Drug Name & Strength	Qty approvable for Atopic Dermatitis
2	2	Dupixent 300mg/2ml SC injection	4 for first 28 days then 2 per 28 days

References:

1. Dupixent injection prescribing information. Tarrytown, NY. Regeneron Pharmaceuticals, Inc.; Mar 2017.
2. Eichenfield, LF, Tom WL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *Journal of the American Academy of Dermatology.* U.S. National Library of Medicine, Feb 2014. Web. 23 Mar. 2017.

Criteria created 9/2017

NONFORMULARY	
Brand Name	**Generic Name**
INGREZZA	valbenazine

CRITERIA FOR COVERAGE/NON-COVERAGE

Ingrezza is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia. The initial dose is 40 mg once daily. After one week, it is increased to a recommended dose of 80 mg once daily.

Ingrezza will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Member must be > 18 years old.

2. The diagnosis has been clinically established by, or in consultation with, a neurologist or a psychiatrist.

3. Ingrezza is to be used for the treatment of symptomatic, moderate to severe tardive dyskinesia (TD). Symptomatic, moderate to severe TD is defined as one of the following (a or b):
   a. Documentation within 90 days of member's baseline score defined with one of the following assessment tools:
      i. Abnormal Involuntary Movement Scale (AIMS) with a score of 3 or 4 on item 8 (severity of abnormal movement overall).
      ii. Extrapyramidal Symptom Rating Scale (ESRS) score ≥ 4.
   b. Patient has been clinically diagnosed with TD by meeting ***all*** DSM-V Criteria (i, ii and iii):
      i. Involuntary athetoid or choreiform movements.
      ii. History of treatment with a neuroleptic agent (i.e. antipsychotic).
      iii. Symptoms lasting longer than 8 weeks.

4. The member must have been prescribed and is currently taking a drug that has tardive dyskinesia as a documented adverse reaction (see Table 1 for a list of drugs).

5. An inadequate treatment response, intolerance or contraindication to both of the following treatments:
   a. Clonazepam trial for three months.
   b. Amantadine trial for at least two months.

6. Documentation the member is not at a significant risk for suicidal or violent behavior and does not have unstable psychiatric symptoms.

7. Documentation of recent (within 90 days) Child-Pugh score and the requested dose is appropriate per the FDA Ingrezza prescribing information. Child Pugh Class B or C (≥ 7) is considered moderate to severe hepatic impairment and the recommended Ingrezza dose is 40 mg once daily.

Exclusions from coverage:
1. Dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors such as reserpine or Xenazine (tetrabenazine).
2. Concomitant use of a monoamine oxidase inhibitor (MAOI) such as selegiline, Nardil (phenelzine), tranylcypromine, or Marplan (isocarboxazid).
3. Use as a preventative agent for the development of tardive dyskinesias.

Quantity approvable: #30 per 30 days of the 40mg or 80mg capsules.

Approval length: 3 months initially then 1 year thereafter.

Continuation criteria:

1. Documented symptom improvement evidenced in the past 90 days by using ONE of the following scores:
   a. AIMS – decrease from baseline by at least 2 points.
   b. ESRS – decrease from baseline by at least 4 points.

Table #1. Medications that can cause TD *(Vijayakumar and Jankovic 2016)*

Class	Drugs within the class		
First Generation Anti-psychotics (FGAs)	chlorpromazine chlorprothixene droperidol fluphenazine flupentixol haloperidol levomepromazine	loxapine mesoridazine molindone perazine perphenazine pimozide	prochlorperazine thioridazine thiothixene trifluoperazine trifluprazine zuclopentixol
Second Generation Anti-psychotics (SGAs)	amisulpride aripiprazole asenapine clozapine iloperidone	levosulpiride lurasidone olanzapine paliperidone quetiapine	remoxipride risperidone sulpiride tiapride ziprasidone
Antiemetics	cisapride clebopride metoclopramide		
Calcium Channel Blockers	cinnarizine flunarizine		
Serotonin reuptake/serotonin norepinephrine reuptake inhibitors	duloxetine citalopram		
Tricyclic antidepressants	amoxapine		
Central monoamine oxidase inhibitors	reserpine		
Anti-manic agents	lithium	sulpiride	veralipride

References:

1. AIMS: Abnormal Involuntary Movements Scale www.cqaimh.org/pdf/tool_aims.pdf
2. Bhidayasiri R, Fahn S, et al. Evidence-based guideline: Treatment of tardive syndromes: Report of the guidelines development subcommittee of the American Academy of Neurology. *Neurology*. 2013;81;463-469.
3. Ingrezza prescribing information. San Diego, CA. Neurocrine Biosciences, Inc.; Apr 2017.
4. American Psychiatric Association (2013). Medication-induced movement disorders and other adverse effects of medication. In Diagnostic and statistical manual of mental disorders (5th ed.). Available at: www.dx.doi/full/10.1176/appi.books.9780890425596.MedicationInduced#x45151.2829056
5. Hauser R, et al. KINECT-3: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Valbenazine for Tardive Dyskinesia. *American Journal of Psychiatry*. 2017 Mar 21: 1-9.
6. Vijayakumar D, Jankovic J. Drug-induced dyskinesia, part 2: Treatment of tardive dyskinesia. *Drugs.* 2016;76:779-787.
7. Chouinard G, Margolese HC. Manual for the Extrapyramidal Symptom Rating Scale (ESRS). *Schizophrenia Research* 76 (2005) 247 – 265.
8. Gharabawi GM, Bossie CA, et al. Abnormal Involuntary Movement Scale (AIMS) and Extrapyramidal Symptom Rating Scale (ESRS): cross-scale comparison in assessing tardive dyskinesia. *Schizophr Res* 2005 Sep 15;77(2-3):119-28.

Criteria created 9/2017

Criteria Name
NON FORMULARY Oral Oncology Drugs

CRITERIA FOR COVERAGE/NONCOVERAGE

Non Formulary oral oncology medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by an oncologist or by a mid-level clinician directly supervised by an oncologist.

2. Requested medication(s) and the diagnosis must meet either a, b, or c.

If the request is for a regimen comprised of more than one oncology drug, including injectable or infused drugs, then the entire regimen still needs to be reviewed to meet either a, b, or c listed below.

a. **FDA indication.** Documentation must be submitted that the requested drug or regimen meets the FDA indication(s) in full. ***In full*** is defined as following the specified indication, strength and directions, including dosing cycle if applicable, any genetic testing requirements and acknowledging any applicable black box warnings.

b. **Compendia.** If the FDA indication is not met in full, then the request is considered *off-label* and must meet one of the following compendia.

i. American Hospital Formulary Service (AHFS) Compendium.
ii. Micromedex/DrugDex Compendium with a ***Class I, IIa, or IIb rating.***
iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a ***strong recommendation.***
iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and a Strong recommendation.***
v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) ***Category of 1, 2A, or 2B.***

c. **Evidence.** If the FDA indication or compendia is not met then **two** published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug or drug regimen and the diagnosis can be submitted for review. The clinical trials must be consistent with the drug or drug regimen requested including the dosing and/or dosing cycle. The conclusion by the trial authors must include that it is considered safe and effective for the requested use.

Clinical Trial Phases:

- **Preclinical research:** A trial done in a lab and not tested in animals or humans.
- **Phase 0:** The first clinical trials to be done among people. In these trials a very small dose of a drug is given to about 10 to 15 people.
- **Phase I**: An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects.
- **Phase II**: An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete.
- **Phase III**: Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way.
- **Phase IV**: After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment's risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials.

3. Documentation required *(ALL must be met unless indicated.):*

a. Chart notes dated within 3 to 6 months supporting the oncology diagnosis and treatment plan. Treatment plan must include the drug or the drug regimen requested.
b. Lab work pertaining to drug or drug regimen requested. All of the below may or may not be applicable.
    i. Genetic test lab report(s) to support a specific mutation.
        Example: The FDA indication for Tagrisso© requires mutation T790M be present.
    ii. Other lab report(s) to support the diagnosis.
        Example: The FDA indication for Ibrance© requires the patient to be HER2 negative and hormone receptor (HR) positive. Both labs would be required to be submitted.
    iii. Hepatic or renal function or other labs that would affect the approvable quantity if impairment exists.
        Example: For capecitabine if moderate renal impairment exists then the dose should be reduced by 25% per the dosage and administration section of the drug label.

4. Approval duration *(one of the below):*
a. Approve for one cycle if the duration requested for one cycle is specific only to that drug or drug regimen and strength.
Example: Capecitabine or temozolomide may be initially prescribed to be taken every day with radiation for 5 weeks. The total duration approved would be 5 weeks. Additional cycles are typically for a different strength and duration in length.
b. Approve for 3 months for active cancer diagnoses.
Examples: Metastatic breast or prostate cancer.
c. Approve for 6 months for cancers in remission or if maintenance therapy.
Examples: Multiple myeloma or CML.

5. Approvable quantity:
a. Initial authorizations for the first two fills will be limited to a 14 day supply (partial-fill) to confirm the patient has experienced an objective response to therapy and is tolerating the therapy well.

6. Continuation criteria (all must be met):
a. Chart notes documenting a positive response to cancer therapy and no intolerable side effects.
b. Lab work and/or radiographic evidence demonstrating a response or continued response to therapy as supported by NCCN, ASCO, the prescribing drug label or other oncology guidelines.
Examples:
- *A decrease from baseline of PSA for prostate cancer (may need scan also submitted).*
- *A decrease from baseline BCR-ABL lab for CML.*
- *A scan that supports no disease progression or a decreased CEA level from baseline for breast cancer.*
- *A decreased from baseline of monoclonal protein, IG levels, FLC's (free light chains), or beta-2-microglobulin for multiple myeloma.*

References:

1. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
3. American Society of Clinical Oncology (ASCO). ASCO Guidelines, Tools, & Resources. 2017.
4. Facts & Comparisons Answers. Available at: http://online.factsandcomparisons.com Accessed 7/2017.
5. Micromedex/DRUGDEX. Available at: www.microdexsolutions.com Accessed 7/2017.
6. Arizona Health Care Cost Containment System. AHCCCS Medical Policy Manual. Policy 310-V Prescription Medications/Pharmacy Services. Rev 2/1/2017.

Criteria created 9/2017

Brand Name	Generic Name
NOXAFIL	Posaconazole

CRITERIA FOR COVERAGE/NONCOVERAGE

NOXAFIL (posaconazole) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

1. Oropharyngeal Candidiasis: for the treatment of orophanyngeal candidiasis, including oropharyngeal candidiasis refactory to fluconazole and/or itraconazole in members 13 years and older.

2. Prophylaxis of invasive fungal infections (invasive Aspergillus or Candidiasis) in members 13 years of age and older who are at high risk of developing these infections because of being severely immunocompromised, such as hemotopoietic stem cell transplant (HSCT) recipients with graft versus host disease (GVHD), members with hematologic malignancies with prolonged neutropenia from chemotherapy or lung transplant members.

Must be prescribed by or in consult with an Infectious Disease specialist, a transplant specialist or an oncologist.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 11/2016
Criteria last updated: 11/2016

Brand Name	Generic Name
ONFI	clobazam

CRITERIA FOR COVERAGE/NONCOVERAGE

Onfi will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has an FDA approved diagnosis of seizures associated with Lennox-Gastaut Syndrome.
2. Member is 2 years of age or older.
3. Prescribed by, or in consultation with a Neurologist.
4. Member has tried at least two seizure medications.
5. Member will be on a seizure medication while on Onfi.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 11/2016
Criteria last updated: 11/2016

HCA			
FORMULARY ORAL ONCOLOGY DRUGS			
BRAND NAME	**Generic Name**	**BRAND NAME**	**Generic name**
AFINITOR	everolimus	**JAKAFI**	ruxolitinib
AFINITOR DISPERZ	everolimus	**LEUCOVORIN**	leucovorin tablets
ARIMIDEX	anastrozole	**MATULANE**	procarbazine
AROMASIN	exemestane	**NEXAVAR**	sorafenib
CAPRESLA	vandetanib	**REVLIMID**	lenalidomide
CYTOXAN	cyclophosphamide capsules	**SUTENT**	sunitinib
ETOPOPHOS	etoposide	**TARGRETIN capsules**	bexarotene
FARESTON	toremifene	**TARCEVA**	erlotinib
GLEEVEC	imatinib	**TASIGNA**	nilotinib
GLEOSTINE	lomustine	**THALOMID**	thalidomide
HEXALEN	altretamine	**TYKERB**	lapatinib
ICLUSIG	ponatinib	**VESANOID (> 26 years old)**	tretinoin capsules
IMBRUVICA	ibrutinib	**VOTRIENT**	pazopanib
INLYTA	axitinib	**XALKORI**	crizotinib
IRESSA	gefitinib	**ZELBORAF**	vemurafenib
		ZOLINZA	vorinostat

CRITERIA FOR COVERAGE/NON-COVERAGE

Formulary oral oncology medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Must be prescribed by an oncologist or by a mid-level clinician directly supervised by an oncologist.**

2. **Requested medication(s) and the diagnosis must meet either a, b, or c.**
   If the request is for a regimen comprised of more than one oncology drug, including injectable or infused drugs, then the entire regimen still needs to be reviewed to meet either a., b., or c. listed below.

   a. **FDA indication.** Documentation must be submitted that the requested drug meets the FDA indication(s) in full. ***In full*** is defined as following the specified indication, strength and directions including dosing cycle if applicable, any genetic testing requirements, and acknowledging any applicable black box warnings.

   b. **Compendia.** If the FDA indication is not met in full, then the request is considered off-label and must meet one of the following compendia.
      i. American Hospital Formulary Service (AHFS) Compendium.
      ii. Micromedex/DrugDex Compendium with a ***Class I, IIa, or IIb rating.***
      iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a ***strong recommendation.***

iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and a Strong recommendation***

v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) ***Category of 1, 2A, or 2B.***

c. **Evidence.** If the FDA indication or compendia is not met then **two** published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug or drug regimen and the diagnosis can be submitted for review. The clinical trials must be consistent with the drug or drug regimen requested including the dosing and/or dosing cycle. The conclusion by the trial authors must include it is considered safe and effective for the requested use.

Clinical Trial Phases:

- **Preclinical research:** A trial done in a lab and not tested in animals or humans.
- **Phase 0:** The first clinical trials to be done among people. In these trials a very small dose of a drug is given to about 10 to 15 people.
- **Phase I**: An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects.
- **Phase II**: An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete.
- **Phase III**: Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way.
- **Phase IV**: After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment's risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials.

3. Documentation required *(ALL must be met unless indicated):*

a. Chart notes dated within 3 to 6 months supporting the oncology diagnosis and treatment plan. Treatment plan must include the drug or the drug regimen requested and current BSA or weight if applicable to support the approvable quantity.

b. Lab work pertaining to drug or drug regimen requested. All of the below may or may not be applicable.

i. Genetic test lab report(s) to support a specific mutation.

Example: The FDA indication for Tagrisso© requires mutation T790M be present.

ii. Other lab report(s) to support the diagnosis.

Example: The FDA indication for Ibrance© requires the patient to be HER2 negative and hormone receptor (HR) positive. Both labs would be required to be submitted.

iii. Hepatic or renal function, or other labs that would affect the approvable quantity if impairment exists.

Example: For capecitabine, if moderate renal impairment exists then the dose should be reduced by 25% per the dosage and administration section of the drug label.

4. Approval duration *(one of the below):*

a. Approve for 1 cycle if the duration requested for one cycle is specific only to that drug or drug regimen and strength.

Example: Capecitabine or temozolomide may be initially prescribed to be taken every day with radiation for 5 weeks. The total duration approvable would be 5 weeks. Additional cycles are typically for a different strength and duration in length.

b. Approve for 3 months for active cancer diagnoses.

Examples: Metastatic breast or prostate cancer.

c. Approve for 6 months for cancers in remission or if maintenance therapy.
Examples: Multiple myeloma or CML.

5. Approvable quantity:

a. Initial authorizations for the first two fills will be limited to a 14 day supply (Partial-Fill) to confirm the patient has experienced an objective response to therapy and is tolerating the therapy well.

6. Continuation criteria *(all must be met):*

a. Chart notes documenting a positive response to cancer therapy and no intolerable side effects.
b. Lab work and/or radiographic evidence demonstrating a response or continued response to therapy as supported by NCCN, ASCO, or other oncology guidelines.
Examples:
- *A decrease from baseline of PSA for prostate cancer (may need scan submitted).*
- *A decrease from baseline BCR-ABL lab for CML.*
- *A scan that supports no disease progression or a decreased CEA level from baseline for breast cancer.*
- *A decreased from baseline of monoclonal protein, IG levels, FLC's (free light chains), or beta-2-microglobulin for multiple myeloma.*

References:

1. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
3. American Society of Clinical Oncology (ASCO). ASCO Guidelines, Tools, & Resources. 2017.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA.
5. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017.

Criteria created: 11/2017

Brand Name	Generic Name
ORKAMBI	Lumacaftor/vacaftor

CRITERIA FOR COVERAGE/NONCOVERAGE

ORKAMBI (lumacaftor/vacaftor) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Criteria for Initial Therapy:

1. Member must be ≥ 6 years of age
2. Member must have a diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test
3. Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation
4. Member must have a baseline FEV1 ≥ 40%
5. Must have documentation of baseline liver function tests (ALT/AST and bilirubin)
6. If member is < 18 years of age, must have a baseline ophthalmological exam to monitor for lens opacities/cataracts

Criteria for Continuation of therapy:

1. Prescriber must provide documentation that member is tolerating and responding to medication (i.e. stable or improved FEV1, weight gain, decreased exacerbations, etc.)
2. Adherence to therapy is confirmed (supported by documentation from patient's chart notes or electronic claim history)
3. Liver function tests (ALT/AST and bilirubin) provided with each renewal during first year of treatment and annually thereafter
    a. ALT or AST does not exceed 5 times the upper limit of normal
    b. ALT or AST does not exceed 3 times upper limit of normal with bilirubin greater than 2 times upper limit of normal

Authorization for continued use shall be reviewed at least every 6 months to confirm there are no contraindications to therapy.

References
Orkambi Package Insert. 09/2016
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Non-Formulary PCSK 9 Agent - Brand Name (Generic)

PRALUENT (alirocumab)

CRITERIA FOR COVERAGE/NONCOVERAGE

PCSK 9 Inhibitors will be considered for coverage under the pharmacy benefit when the following criteria are met:

Criteria for Initial Therapy:

1. Member must be ≥ 18 years of age
2. Must be prescribed by, or in with, a cardiologist, endocrinologist, or lipid specialist
3. Must have clinical documentation of ONE of the following diagnoses:
    a. Must have diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by one of the following:
        i. Diagnosis confirmed by DNA-based evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation
        ii. Diagnosis confirmed by clinical criteria as "definite FH" using WHO/Dutch Lipid Network with a score 9 or higher using the WHO/Dutch Lipid Network criteria
        iii. Diagnosis confirmed by clinical criteria using Simon Broome criteria with a total cholesterol > 290mg/dL or LDL cholesterol > 190mg/dL AND tendon xanthomas in patient, or in 1st degree relative (parent, sibling, child), or in 2nd degree relative (grandparent, uncle, aunt)
    b. Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:
        i. Acute coronary syndromes
        ii. History of myocardial infarction
        iii. Stable or unstable angina
        iv. Coronary or other arterial revascularization
        v. Stroke
        vi. Transient ischemic attack
        vii. Peripheral arterial disease presumed to be of atherosclerotic origin
4. Appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment, supported by documentation of counseling in chart notes
    a. Total dietary fat < 35% of total calories
    b. Weight loss in overweight patients
    c. Aerobic exercise
    d. Diet rich in fruits and vegetables
5. Baseline and current LDL-C is provided
6. Require additional LDL-C reduction after 90-day trial of a high-intensity statin at maximum dosage (atorvastatin 80mg or rosuvastatin 40mg) in combination with ezetimibe. Additional LDL-C reduction defined as an inadequate response to therapy by not achieving ≤ 50% reduction in LDL-C from baseline or LDL-C is ≥ 100 mg/dL with ASCVD or is ≥ 130 mg/dL without ASCVD
7. Contraindication/intolerance to a high intensity statin defined as ONE of the following:
    a. A labeled contraindication to all statins as documented in medical records
    b. Member has experienced documented rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN
    c. Member has undergone a trial of a statin rechallenge (i.e. pravastatin 10-40 mg or rosuvastatin 5 mg) with documented reappearance of muscle symptoms such as myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks)
    d. Member is unable to tolerate low-, moderate-, and high-intensity statins as evidenced by documented myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks)
8. Patient has been adherent to lipid-lowering therapy, defined as proportion of days covered (PDC) ≥ 80%
9. Will be used in combination with a maximally tolerated statin

Criteria for Continuing Therapy:

A. Current LDL-C level provided to assess response to medication
B. Documentation supports a sustained LDL-C reduction from pre-treatment baseline (e.g., prior to Praluent therapy) while on Praluent therapy.
C. The member is tolerating the medication
D. Medication will continue to be used in combination with a maximally tolerated statin
E. Patient has remained adherent to statin therapy, defined as proportion of days covered (PDC) ≥ 80%

Authorization for Initial approval: 3 months and renewal approval: One year
Quantity Limit: 2/28 days

References:

1. Praulent Prescribing Information. Bridgewater, New Jersey. Sanofi-Aventis, LLC. Revised April 2017. Accessed 6/2017. Available at: www.products.sanofi.us/praluent/praluent.pdf
2. Jacobson T, Ito M, Maki K, et al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1 – Full Report. J Clin Lipidol. 2015;9(2): 129-169. Available at: http://www.lipidjournal.com/article/S1933-2874(15)00059-8/fulltext
3. Lloyd-Jones DM, Morris PB, Ballantyne CM et al. 2016 Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2016;Apr 1. Available at: www.acc.org/latest-in-cardiology/ten-points-to-remember/2016/03/30/11/58/2016-acc-expert-consensus-decision-pathway-on-the-role-of-nonstatin
4. Stone N, Robinson J, Lichtenstein AH et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014;129(25 Suppl.2):S1–S45.
5. UpToDate. www.uptodate.com Accessed 6/2017
6. Micromedex/DRUGDEX at www.microdexsolutions.com Accessed 6/2017

Last reviewed and updated: 6/2017

Non-Formulary PCSK 9 Agent - Brand Name (Generic)

REPATHA (evolocumab)

CRITERIA FOR COVERAGE/NONCOVERAGE

REPATHA will be considered for coverage under the pharmacy benefit when the following criteria are met:

Criteria for Initial Therapy (Initial authorization will be for 3 months):

1. Member must be ≥ 18 years of age except for the diagnosis of homozygous familial hypercholesterolemia in which member must be ≥ 13 year of age
2. Must be prescribed by, or in conjunction with, a cardiologist, endocrinologist, or lipid specialist
3. Must have clinical documentation of one of the following diagnoses:
    a. Must have diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by one of the following:
        i. Diagnosis confirmed by DNA-based evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation
        ii. Diagnosis confirmed by clinical criteria as "definite FH" using WHO/Dutch Lipid Network with a score 9 or higher using the WHO/Dutch Lipid Network criteria
        iii. Diagnosis confirmed by clinical criteria using Simon Broome criteria with a total cholesterol > 290mg/dL or LDL cholesterol > 190mg/dL AND tendon xanthomas in patient, or in 1st degree relative (parent, sibling, child), or in 2nd degree relative (grandparent, uncle, aunt)
    b. Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:
        i. Acute coronary syndromes
        ii. History of myocardial infarction
        iii. Stable or unstable angina
        iv. Coronary or other arterial revascularization
        v. Stroke
        vi. Transient ischemic attack
        vii. Peripheral arterial disease presumed to be of atherosclerotic origin
    c. Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by ONE of the following:
        i. Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)
        ii. Both of the following:
            1. Either untreated/pre-treatment LDL-C > 500 mg/dL or treated LDL-C > 300 mg/dL
            2. Xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents
4. Appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment, supported by documentation of counseling in chart notes
    a. Total dietary fat < 35% of total calories
    b. Weight loss in overweight patients
    c. Aerobic exercise
    d. Diet rich in fruits and vegetables
5. Baseline and current LDL-C is provided
6. Require additional LDL-C reduction after 90-day trial of a high-intensity statin at maximum dosage (atorvastatin 80mg or rosuvastatin 40mg) in combination with ezetimibe. Additional LDL-C reduction defined as an inadequate response to therapy by not achieving ≤ 50% reduction in LDL-C from baseline or LDL-C is ≥ 100 mg/dL with ASCVD or is ≥ 130 mg/dL without ASCVD
7. Contraindication/intolerance to a high intensity statin defined as ONE of the following:
    a. A labeled contraindication to all statins as documented in medical records

b. Member has experienced documented rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN
c. Member has undergone a trial of a statin rechallenge (i.e. pravastatin 10-40 mg or rosuvastatin 5 mg) with documented reappearance of muscle symptoms such as myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks)
d. Member is unable to tolerate low-, moderate-, and high-intensity statins as evidenced by documented myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks)

8. Patient has been adherent to lipid-lowering therapy, defined as proportion of days covered (PDC) ≥ 80%
9. Will be used in combination with a maximally tolerated statin

Criteria for Continuing Therapy (Renewal authorization will be for 12 months):

A. Current LDL-C level provided to assess response to medication
B. Documentation supports a sustained LDL-C reduction from pre-treatment baseline (e.g., prior to Praluent therapy) while on Praluent therapy.
C. The member is tolerating the medication
D. Medication will continue to be used in combination with a maximally tolerated statin
E. Patient has remained adherent to statin therapy, defined as proportion of days covered (PDC) ≥ 80%

Quantity Limit: Heterozygous familial hypercholesterolemia (HeFH) and ASCVD: 2/28 days

References:

1. Repatha prescribing information. Thousand Oaks, CA. Amgen Inc. Revised 7/2016. Accessed 6/2017. Available at: www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/repatha/repatha_pi_hcp_english.ashx
2. Jacobson T, Ito M, Maki K, et al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1 – Full Report. J Clin Lipidol. 2015;9(2): 129-169. Available at: http://www.lipidjournal.com/article/S1933-2874(15)00059-8/fulltext
3. Lloyd-Jones DM, Morris PB, Ballantyne CM et al. 2016 Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2016;Apr 1. Available at: www.acc.org/latest-in-cardiology/ten-points-to-remember/2016/03/30/11/58/2016-acc-expert-consensus-decision-pathway-on-the-role-of-nonstatin
4. Stone N, Robinson J, Lichtenstein AH et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014;129(25 Suppl.2):S1–S45.
5. UpToDate. www.uptodate.com Accessed 6/2017
6. Micromedex/DRUGDEX at www.microdexsolutions.com Accessed 6/2017

Last reviewed and updated: 6/2017

Brand Name	Generic Name
PEGASYS®	Peginterferon alfa-2a
PEGINTRON®	Peginterferon alfa-2b

CRITERIA FOR COVERAGE/NONCOVERAGE

- Patient has a diagnosis of chronic hepatitis C with compensated liver disease
  AND
- Patient will be receiving combination therapy with other hepatitis C virus antiviral drugs (i.e. Ribavirin ± NS3/4A protease inhibitor)

OR

- Patient has a diagnosis of chronic hepatitis B

AND

- Patient has evidence of hepatitis B viral replication

AND

- Patient has been serum hepatitis B surface antigen (HBsAg)-positive for at least 6 months

AND

- Patient does not have any of the following contraindications to therapy:
  - Uncontrolled depression
  - Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon and ribavirin

Pegasys (peginterferon alfa-2a) is subject to a duration limit depending on the diagnosis, therapy, and patient type.

PegIntron (peginterferon alfa-2b) is considered experimental/investigational for conditions not listed in this coverage policy section.

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 09/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 09/2016
Criteria last reviewed and updated: 09/2016

Brand Name	Generic Name
PROMACTA	eltrombopag

CRITERIA FOR COVERAGE/NONCOVERAGE

PROMACTA/eltrombopag will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Chronic Immune (idiopathic) thrombocytopenic purpura (ITP) for members ≥6 years of age and meet both criteria (a) and (b) below:

    a. Pretreatment platelet count < 30,000/mm3 (30 x 109/L or 30,000/ml) or a platelet count < 50,000/mm3 (50 x 109/L or 50,000/ml) with significant mucous membrane bleeding or risk factors for bleeding

    b. Tried/failed/intolerance to corticosteroids, immunoglobulins (IVIG, IGIV, or anti-Rho[D]), or splenectomy

2. Thrombocytopenia secondary to cirrhosis of the liver due to hepatitis C for members ≥ 18 years of age.

3. Severe aplastic anemia in members ≥18 years of age who have had an insufficient response to immunosuppressive therapy

For reauthorization/continuing treatment, member must meet either (a) or (b) below:

a. Platelet count of at least 50,000/mm3 (after 4 weeks at a maximum dose of 75mg/day),

b. Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

This guideline will be reviewed on an annual basis.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
PULMICORT RESPULES	budesonide

CRITERIA FOR COVERAGE/NON-COVERAGE

PULMICORT RESPULES will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a diagnosis of asthma.
2. The member must meet one of the following age requirements:
    a. The member is 12 months to 8 years of age.
    b. The member is 9 years of age and older AND unable to use an oral aerosol inhaler.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed: 11/2016

Covered Product	Reference BRAND or Generic Name
PULMOZYME®	Dornase alfa
Bethkis – Preferred product	Tobramycin nebulization
Kitabis PAK – Preferred product	Tobramycin nebulization
Tobramycin INH –*NON Preferred*	TOBI® INHALATION *NON Preferred*
TOBI POD HALER – *NON Preferred*	

CRITERIA FOR COVERAGE/NONCOVERAGE

Preferred products- Bethkis and/or Kitabis Pak are required prior to requests for non-preferred tobramycin inhalation products, unless there is a documented intolerance or documented hypersensitivity to both preferred products.

Bethkis and/or Kitabis PAK will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Patient has a diagnosis of cystic fibrosis
2. Patient has evidence of P aeruginosa in the lungs
3. Patient is six years of age or older

Tobramycin solution for inhalation or TOBI PODHALER will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Patient has a diagnosis of cystic fibrosis
2. Patient has evidence of P aeruginosa in the lungs
3. Patient is six years of age or older
4. Patient has tried and failed or has contraindication to Bethkis and Kitabis

PULMOZYME (dornase alfa) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has a diagnosis of cystic fibrosis
- Patient is five years of age or older

Products are subject quantity limits to ensure appropriate use.

Authorization for continued use shall be reviewed at least every 12 months to confirm the following:

- Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations)
- Current coverage policy criteria are met

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
RANEXA®	ranolazine

CRITERIA FOR COVERAGE/NONCOVERAGE

Ranexa is FDA indicated for the treatment of chronic angina. It may be used with beta-blockers, nitrates, calcium channel blockers, antiplatelet therapy, lipid-lowering therapy, ACE inhibitors and angiotensin receptor blockers.
The mechanism of action of its antianginal effects has not been determined. The recommended initial dosing is 500 mg twice daily, and it may be increased to a maximum of 1000 mg twice daily, as needed, based on clinical symptoms.

Ranexa will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic symptomatic angina, and the initial prescription has been written by a cardiologist. Refills may be written by the primary care provider.

2. Within a reasonable therapeutic time period at maximally tolerated doses, the member has tried and failed a beta blocker and a long-acting nitrate alone **and** in combination.

Formulary beta blockers include acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol, sotalol, labetalol and pindolol.
Formulary Long acting nitrates include isosorbide dinitrate, isosorbide mononitrate and nitroglycerin patch.

3. The member does not have any of the following:
   - Hepatic cirrhosis.
   - Pre-existing QT prolongation.
   - Concurrent therapy with a strong CYP3A4 inhibitor such as ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir or saquinavir.
   - Concurrent therapy with a CYP3A4 inducer such as rifampin, rifabutin, rifapentin, phenobarbitol, phenytoin, carbamazepine or St. John's wort.
   - Acute renal failure, particularly in individuals with a baseline CrCL < 30 mL/min.

Approval length: 12 months.
Approvable quantity: Up to 1000 mg twice daily.

Continuation criteria (all must be met):
1. Member's therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the member's condition at that time.
2. Member has been adherent with Ranexa fills unless extenuating circumstances exist (hospitalization, medical procedures, etc.).
3. Documentation the member is tolerating the medication and there continues to be a medical need.
4. Documentation the member has responded to treatment due to a documented decrease in anginal attacks.

References:
1. Ranexa prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev 1/2016.
2. Amsterdam EA, Wenger NK, et al. 2014 AHA/ACC Guideline for the Management of Patients with Non–ST-Elevation Acute Coronary Syndromes. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology.* Vol 64(24) Dec 2014.
3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 7/2017.
4. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 7/2017.
Criteria revised 9/2017

Brand Name	Generic Name
RESTASIS	cyclosporine

CRITERIA FOR COVERAGE/NONCOVERAGE

RESTASIS/cyclosporine will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Member is 16 years or older
2. Member has been clinically diagnosed with Sjogren syndrome (moderate to severe keratoconjunctivitis sicca /chronic dry eye disease (CDED))
3. Prescribed by an ophthalmologist, rheumatologist or optometrist
4. Member has functional lacrimal gland
5. Member has tried/failed/intolerance to any non-prescription wetting agents (e.g., artificial tears) in the form of drops, ointments or gels,
6. There is no presence of current ocular infection (e.g. herpes keratitis).
7. Member is not currently taking topical anti-inflammatory drugs or using punctal plugs

Duration of Authorization: 6 months

Recertification: 12 months

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered Products

Ribavirin oral products

CRITERIA FOR COVERAGE/NONCOVERAGE

Ribavirin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

- **Chronic HCV** – In combination with with other hepatitis C virus antiviral drugs for the treatment of chronic HCV in patients 18 years and older with compensated liver disease

AND

- Female: Patient is not pregnant and willing to use contraceptive prevention methods.

AND

- Male: Willing to use contraceptive methods.

AND

- Ribavirin is distributed/dispensed by a designated Specialty Pharmacy.

AND

Approval duration will vary dependent upon patient's genotype and treatment history.

This guideline will be reviewed on an annual basis.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last updated 09/2016

Covered products	Brand or generic Name
Rivastigmine oral capsule	EXELON
Rivastigmine oral solution	EXELON
Rivastigmine patch	EXELON

CRITERIA FOR COVERAGE/NONCOVERAGE

Rivastigmine is an acetylcholinesterase inhibitor indicated for treatment of mild, moderate, and severe dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease.
The recommended dosage of rivastigmine capsules and oral solution in Alzheimer's disease is 6 mg to 12 mg per day, taken twice a day. There is evidence from the clinical trials that doses at the higher end of this range may be more beneficial.
The recommended dosage of rivastigmine capsules and oral solution shown to be effective for dementia associated with Parkinson's disease is 3 mg to 12 mg per day, taken twice a day.
The recommended dosage of rivastigmine patches is as follows:

- Mild to Moderate Alzheimer's Disease and Parkinson's Disease Dementia: 9.5 mg/24 hours or 13.3 mg/24 hours once daily.
- Severe Alzheimer's Disease: 13.3 mg/24 hours once daily.

Rivastigmine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member must be 18 years old or older.

2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.

3. Documented diagnosis of mild to moderate dementia associated with Alzheimer's disease or Parkinson's disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
   a. Between 20 - 24 for mild disease.
   b. Between 13- 20 points for moderate disease.

4. Documented diagnosis of severe dementia associated with Alzheimer's disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of the below.
   a. Less than 13 points for severe disease.

Quantity Limits:
Rivastigmine capsules – Up to #60 per 30 days.
Rivastigmine solution – Up to 180 mL per 30 days.
Rivastigmine patches – #30 per 30 days

Length of Approval: Three months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

Continuation Criteria:
1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score.

Exclusions:

1. Not for use for non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.

References:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 9/9/17.
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Criteria created 9/2017

Brand Name	Generic Name
ROZEREM	Ramelteon

CRITERIA FOR COVERAGE/NONCOVERAGE

Rozerem is a melatonin agonist indicated for the treatment of insomnia characterized by difficulty with sleep onset. The clinical trials performed in support of efficacy were up to 6 months in duration.
The recommended and maximum dose per day is 8 mg taken within 30 minutes of going to bed.

Rozerem will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia characterized by difficulty of sleep onset only. Chronic insomnia defined as difficulty initiating sleep or for at least **three** nights per week and is present for at least **three** months.
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days and failure of each of the following at maximum therapeutic doses:
    a. Zaleplon up to 10 mg.
    b. Zolpidem up to 10 mg.
    c. Temazepam 30 mg or triazolam 0.25 mg.

Note: *An exception can be made to the required trial of the above medications if the member has a documented history of addiction to controlled substances.*

4. The member does not have a diagnosis of severe sleep apnea.

Quantity limits: #30 per 30 days.

Approval Length: Six months then reevaluation needs to occur regarding continued medical necessity.

Continuation criteria:
1. Documentation member is receiving a positive clinical response evidenced by a decrease in nights per week with sleep onset difficulties.

Exclusions:
1. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate).

References:

1. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;12(2):307-349.
2. Rozerem prescribing information Deerfield, IL. Takeda Pharmaceuticals America Inc. Rev 11/2010.

Criteria revised 9/2017

Brand Name	Generic Name
SELZENTRY	Maraviroc

CRITERIA FOR COVERAGE/NONCOVERAGE

SELZENTRY / Maraviroc will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The member must be clinically diagnosed with CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay

2. Member is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

3. Medication must be prescribed by, or in conjunction with, an HIV specialist

Duration of approval: 12 months.
Authorization for continued use shall be reviewed after 12 months to confirm there is documentation of positive clinical response to Selzentry therapy.

References:
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 04/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 04/2017
Criteria last reviewed and updated: 04/2017

Brand Name	Generic Name
SEREVENT DISKUS	salmeterol xinatoate

CRITERIA FOR COVERAGE/NONCOVERAGE

SEREVENT DISKUS will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member must be clinically diagnosed with one of the following disease states and meet their individual criteria:

- Asthma
    a. Member bust be 4 years of age and older
    b. Must be used in combination with an inhaled corticosteroid

- Chronic obstructive pulmonary disease
    a. Member must be 18 years of age and older

- Exercise-induced asthma; prophylaxis
    a. Member bust be 4 years of age and older

- Nocturnal asthma
    a. Member bust be 4 years of age and older
    b. Must be used in combination with an inhaled corticosteroid

Exclusions from coverage include:

- The use of Serevent/salmeterol as monotherapy for the treatment of asthma or nocturnal asthma.
- The use of Serevent/salmeterol when dosed more than twice a day (12 hours apart).

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed: 11/2016

Brand Name	Generic Name
SENSIPAR	Cinacalcet

CRITERIA FOR COVERAGE/NONCOVERAGE

SENSIPAR will be considered for coverage when the following criteria are met:

Initial approval will be for 3 months, if the patient meets the guidelines for continuation of therapy than approval can be extended for 6 months and then 12 months thereafter

- Patient must have one of the following documented clinical conditions:
  - Secondary hyperparathyroidism due to chronic kidney disease on dialysis; AND
    - iPTH levels must be >300pg/mL (biPTH > 160) and Ca > or = 8.4 mg/dL in order to initiate therapy; AND

      Must have tried and failed or intolerant to:
      - Calcium acetate or a Non-calcium phosphate binder" (i.e., Renagel, etc.);

        AND Vitamin D/Vitamin D analog" (i.e., calcitriol, Hectorol, etc.).; OR
  - Hypercalcemia due to parathyroid carcinoma; AND
    - iPTH levels must be >300pg/mL (biPTH > 160) and Ca > or = 8.4 mg/dL in order to initiate therapy; OR
  - Severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy;AND
    - iPTH levels must be >300 pg/mL (biPTH > 160) and Ca > or = 8.4 mg/dL in order to initiate therapy.

Criteria for Continuation of Therapy:

- iPTH levels must be greater than 150 pg/ml and calcium must be greater than or = 8.4 mg/dL

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed: 03/2017

Brand Name	Generic Name
SIGNIFOR	pasireotide

CRITERIA FOR COVERAGE/NONCOVERAGE

SIGNIFOR® (pasireotide) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has a diagnosis of (pituitary) Cushing's disease

AND

- Patient is 18 years of age or older

AND

- Pituitary surgery is not an option or has not been curative

Authorization for continued use shall be reviewed at 12 months to confirm that the patient has experienced an objective response to therapy (i.e., clinically meaningful reduction in 24-hour urinary free cortisol levels and/or improvement in signs or symptoms of the disease).

SIGNIFOR (pasireotide) is subject to a quantity limit of 2 units/day.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered Product	Reference Brand
Sildenafil 20mg tablets	REVATIO

CRITERIA FOR COVERAGE/NONCOVERAGE

Sildenafil 20mg tablets (REVATIO) will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by a cardiologist or Pulmonologist
2. Clinical diagnosis of pulmonary hypertension WHO group 1 (defined by pulmonary artery pressure greater than 25mmHg at rest or greater than 30mm Hg with excertion)
3. Member must be in NYHA class II-IV
4. If brand name drug, Revatio, is requested, member must have tried and failed or intolerant to sildenafil
5. Member is not on current Nitrate therapy
6. Member must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test
7. Member has been evaluated for retinitis pigmentosa and completed counseling on the risk of ocular disturbances, non-arteric anterior ischemic optic neuropathy (NAION), and potential for blindness.

**The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.

Duration of Authorization (initial and renewal): 12 months

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017
Criteria last reviewed and updated: 03/2017

Brand Name	Generic Name
SILENOR	Doxepin

CRITERIA FOR COVERAGE/NONCOVERAGE

Silenor is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance. The clinical trials performed in support of efficacy were up to three months in duration.
The recommended and maximum dose of Silenor for adults is 6 mg once daily. A 3 mg once daily dose may be appropriate for some patients, if clinically indicated.

Silenor will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia characterized by difficulty with sleep maintenance only. Chronic insomnia defined as difficulty maintaining sleep for at least **three** nights per week and is present for at least **three** months.
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days and failure of each of the following at the maximum therapeutic doses:
    a. Zolpidem 10 mg.
    b. Temazepam 30 mg.

Note: *An exception can be made to the required above medications regarding prior trial and failure if the patient has a documented history of addiction to controlled substances.*

4. The member does not have a diagnosis of severe sleep apnea.

Quantity limits: #30 per 30 days**.**

Approval Length: Six months then reevaluation needs to occur regarding continued medical necessity.

Continuation criteria:
1. Documentation member is receiving a positive clinical response evidenced by a decrease in nights per week with sleep maintenance difficulties.

Exclusions:
1. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate).

References:

1. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;12(2):307-349.
2. Silenor prescribing information. Morristown, NJ. Pernix Therapeutics. Rev 03/2010.

Criteria created 9/2017.

Brand Name	Generic Name
SIVEXTRO	Tedizolid phosphate

CRITERIA FOR COVERAGE/NONCOVERAGE

Sivextro (tedizolid phosphate) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has been clinically diagnosed with Acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of gram-positive microorganisms (namely, Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin- susceptible [MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis.)

2. Culture and sensitivity indicates susceptibility to tedizolid (SIVEXTRO)

3. Member must have tried/failed/contraindication to preferred prior authorized alternative: linezolid

4. Member not taking Zyvox (linezolid) concurrently.

5. Quantity Limit: 200mg once daily: 6 tablets /30 days; one dose per day for six days.

Authorization will be for duration of therapy not to exceed 6 days of therapy (including doses given in hospital, emergency room, or urgent care). Additional course of therapy will require new PA submission and clinical notes documenting response and need for additional therapy.

This guideline will be reviewed on an annual basis.

References:
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
SIVEXTRO prescribing information. Cubist Pharmaceuticals, Inc. Lexington, MA. June 2014.
Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. Clin Infect Dis. 2014;59(2):e10-52.
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
SKLICE	Ivermectin

CRITERIA FOR COVERAGE/NONCOVERAGE (HC)

Sklice (ivermectin) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

- **For the topical treatment of head lice infestations in patients 6 months or older.**

AND

- Documented use and failure on HC Formulary products: permethrin.

Approval duration is 1 month.

This guideline will be reviewed on an annual basis.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered Product	Reference Brand Name
Tacrolimus Ointment (0.03% & 0.1%)	PROTOPIC

CRITERIA FOR COVERAGE/NONCOVERAGE

Tacrolimus Ointment will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has been diagnosed with:
  - Atopic Dermatitis (eczema)

AND

- Patient has tried and failed an adequate course of therapy with at least two generic prescription formulary topical steroids in the past 180 days unless contraindicated.

AND

- Patient is at least 15 years of age for the 0.1% dosage

AND

- Patient is at least 2 years of age for the 0.03% dosage

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References:
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 09/2016
Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 09/2016
Criteria last reviewed and updated: 9/2016

Covered Products	Approved generic or brand name
testosterone injection (cypionate or enanthate)	Depo-testosterone/Delatestryl
testosterone topical 1% gel (pkts and pump)	Androgel 1%
testosterone topical solution	Axiron
ANDRODERM PATCH	testosterone
ANDROGEL 1.62%-	testosterone

CRITERIA FOR COVERAGE/NONCOVERAGE

First-line: Testosterone cypionate or testosterone enanthate injectable
Second-line: Generic testosterone topical 1% gel (packets or pump) or generic topical solution
Third-line: Androderm or Androgel 1.62%

Testosterone replacement therapy will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Criteria for Males:

1. Chart notes must be submitted documenting the trial of **first-line** injectable testosterone agents according to the following criteria before a topical second or third-line agent can be reviewed for use:
   - Demonstrable failure of a first-line testosterone trial lasting at least 90 days, evidenced by a baseline serum total testosterone level and a second level demonstrating a sub-therapeutic level despite following a 90 day documented trial of adherent intramuscular testosterone therapy *(see below)*; OR
   - Intolerance to a first-line testosterone agent; OR
   - Needle phobia to a degree that it meets *DSM-V-TR 300.29* (Specific Phobia).

2. Members must be clinically diagnosed with documentation with one of the following disease states:
   a. **Primary hypogonadism** *(hypergonadotropic hypogonadism)* that is congenital or acquired and is documented to be due to *one* of the following:
      i. Cryptorchidism.
      ii. Bilateral torsion.
      iii. Orchitis.
      iv. Vanishing testis syndrome.
      v. Orchidectomy.
      vi. Klinefelter syndrome.
      vii. Chemotherapy.
      viii. Toxic damage from alcohol or heavy metals.
   b. **Secondary hypogonadism** *(hypogonadotropic hypogonadism)* evidenced by documentation of one of the following:
      i. Idiopathic gonadotropin- or luteinizing hormone-releasing hormone (LHRH) deficiency supported by laboratory reports of GnRH testing (e.g., Kallman syndrome).
      ii. Pituitary or hypothalamic injury, such as from tumors, trauma or radiation.

3. The following laboratory reports are required to be submitted prior to initiation of therapy and to be drawn within 30 days:

a. At least **two low** (less than 200 ng/dL) **total** testosterone levels drawn prior to 10 AM on two separate days.

Note: *Testosterone levels vary from hour to hour. Periodic declines below the normal range can occur in some otherwise normal men. An overall diurnal rhythm is also present, the highest levels of circulating testosterone occurring during the early morning hours. Therefore, testosterone levels should be determined in the morning, and studies should be repeated in patients with subnormal levels, especially those with no definite signs or symptoms of hypogonadism.*[5]

b. An LH and an FSH level consistent with the diagnosis requested.
   - **Primary** hypogonadism exhibits elevated LH and FSH levels.
   - **Secondary** hypogonadism exhibits low or inadequately normal LH and FSH levels.

Note*: If a low testosterone level has been established, further laboratory testing is used to determine whether the hypogonadism is related to a primary testicular disorder (hypergonadotropic hypogonadism) or to pituitary disease (hypogonadotropic hypogonadism*).[5] *In patients with signs and symptoms indicative of hypogonadism, determining luteinizing hormone (LH) and follicle-stimulating hormone (FSH) levels together with the initial testosterone level is usually most efficient.*[5]

Exclusions for male testosterone replacement therapy:
1. Treatment of "age-related hypogonadism" or "late-onset hypogonadism" alone.[6]
2. Treatment of any symptoms considered to be for reasons related to cosmetic, sexuality or fertility alone. This includes indications related to increased body fat, infertility, erectile dysfunction, a decrease in size or firmness of testicles, decreased beard and body hair growth and decreased sex drive/libido. Any number of these indications alone are not qualifying conditions for testosterone replacement therapy.
3. If member is concurrently taking an anti-androgen medication (e.g. Zytiga, bicalutamide, Xtandi, flutamide, or nilutamide).
4. Use of two testosterone products concurrently (i.e. a topical plus an injectable).

Approvable dosing and quantity for hypogonadism in males:
- *Testosterone cypionate or enanthate injection:* 50 to 200 mg should be administered every two weeks up to maximum of 400 mg every four weeks. Once-a-week dosing is not supported by the FDA indication. Doses greater than 400 mg per month are generally not required because of the prolonged action of these preparations and will require prior authorization for review.
- *Testosterone topical gel and solution, Androderm and Androgel 1.62%:* The maximum dosing as specified per the prescribing information.

Approval length for hypogonadism in males: 3 months initially then up to 12 months thereafter dependent on clinical response.

Continuation of therapy criteria for hypogonadism in males:
1. Recent (within 90 days) total testosterone labs reflecting within reference range testosterone levels.
2. Adherence to prescription filling per claims history. If the member is not adherent to the regimen, then the appropriateness of the treatment plan shall be reevaluated and discussed with the prescribing provider.

Criteria for Males with Delayed Puberty (testosterone enanthate injection only):

1. Delayed puberty (testosterone enanthate injection): To stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief occasional treatment with conservative doses may be justified if these patients do not respond to psychological support. Discuss the potential adverse effect on bone maturation with the patient and parents prior to androgen administration. To assess the effect of treatment on the epiphyseal centers, obtain an x-ray of the hand and wrist to determine bone age every 6 months.
2. Testosterone levels must be submitted initially and subsequently for renewal requests.

Criteria for Females (testosterone enanthate injection only):

1. Member is not currently taking an anti-androgen medication (e.g., Zytiga, bicalutamide, Xtandi, flutamide, or nilutamide).
2. Members must be clinically diagnosed with metastatic mammary cancer: This may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy include ablation of the ovaries. This treatment has been used in premenopausal women with breast cancer who have benefited from oophorectomy and have a hormone-responsive tumor. Pregnancy Category is X.

Criteria for diagnosis of Gender Dysphoria (testosterone cypionate injection only):

1. May be used in female-to-male transsexuals with a diagnosis of Gender Identity Disorder.
2. Member is not currently taking an anti-androgen medication (e.g., Zytiga, bicalutamide, Xtandi, flutamide, or nilutamide).

**Testosterone lab testing is NOT required if patient has a diagnosis of Gender Dysphoria.

Continuation Criteria for use in males with delayed puberty, for use in females with mammary cancer, or for gender identity disorder: Authorization for continued use shall be reviewed at least every twelve months to confirm response and that there are no contraindications to therapy.

References:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 8/2017.
2. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 08/2017.
3. PubMed Article: http://www.ncbi.nlm.nih.gov/ Accessed 09/2016.
4. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. Jun;95(6):2536-59.
5. Petak, SM. American Association of Cllinical Endocrinologists medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update. *Endrocrine Practice.* Vol 8 No. 6 Nov/Dec 2002.
6. FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use. Available at: www.fda.gov/Drugs/DrugSafety/ucm436259.htm. Mar 2015.
7. Depo-Testosterone prescribing information. New York, NY. Pharmacia & Upjohn Co. Rev 10/2016.
8. Delatestryl prescribing information. Malvern, PA. Endo Pharmaceuticals. Rev 10/2016.
9 American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders: DSM-5. Washington, D.C: American Psychiatric Association.

Criteria revised: 9/2017

Brand Name	Generic Name
TRACLEER	bosentan

CRITERIA FOR COVERAGE/NONCOVERAGE

TRACLEER (BOSENTAN) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by a Cardiologist, or Pulmonologist
2. Member must be clinically diagnosed with one of the following disease states
    a) Pulmonary hypertension WHO group I; WHO Class III or IV
    b) Eisenmenger's syndrome (WHO functional class III pulmonary arterial hypertension)
    c) Chronic thromboembolic pulmonary hypertension
3. Member is not utilizing Flolan or Remodulin
4. Member has tried and failed or has an intolerance to a calcium channel blocker.

Authorization for continued use shall be reviewed at least every 12 months to confirm that the patient has not experienced disease progression.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
TRAVATAN Z	Travoprost 0.004%

CRITERIA FOR COVERAGE/NONCOVERAGE

Travatan Z or Travoprost 0.004% ophthalmic solution will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Member has been diagnosed with:
  - Elevated intraocular pressure associated with open-angle glaucoma
  - Elevated intraocular pressure associated with ocular hypertension

AND

- Member must try and fail latanoprost (generic Xalatan).

AND

- Member is at least 16 years of age

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
TRUVADA	Emtricitabine/Tenofovir Disoproxil Fumarate

CRITERIA FOR COVERAGE/NONCOVERAGE

TRUVADA/ Emtricitabine/Tenofovir Disoproxil Fumarate will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a diagnosis of HIV-1 infection and are on other antiretrovirals for the treatment of HIV-1 infection
2. Prescribed by or in consultation with an HIV or Infectious Disease specialist

Approval duration: 12 months

Exclusions from coverage include:

- When used for its Pre-Exposure Prophylaxis (PrEP) indication
- When used for monotherapy of HIV-1 infection

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts&ComparisonseAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last updated: 11/2016

Brand Name	Generic Name
VENTAVIS®	iloprost
TYVASO®	treprostinil

CRITERIA FOR COVERAGE/NONCOVERAGE

Ventavis (iloprost), or Tyvaso (treprostinil) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by or in consultation with a pulmonologist.
2. Member has a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I
3. Diagnosis was confirmed by right heart catheterization
4. New York Heart Association (NYHA) Functional Class requirements:
    a. For Ventavis (iloprost): NYHA Functional Class III to IV symptoms
    b. For Tyvaso (treprostinil): NYHA Functional Class II to III symptoms

Quantity Limit

- Ventavis (iloprost) is subject to a quantity limit of 9 ampules per day.
- Tyvaso (treprostinil) is subject to a quantity limit of 1 ampule per day.

If the above criteria are met, the length of authorization is 6 months for initial and 12 months for renewals. Prostanoids are considered experimental/investigational for conditions not listed in this coverage policy section.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
VIGAMOX OPTHALMIC SOLUTION	moxifloxacin

CRITERIA FOR COVERAGE/NONCOVERAGE (HC)

Vigamox ophthalmic solution (moxifloxacin) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

1. **Bacterial conjunctivitis:** For the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:
   Aerobic gram-positive microorganisms: *Aerococcus viridans*, *Corynebacterium macginlegi*, *Corynebacterium* species, *Enterococcus faecalis*, *Micrococcus luteus*, *Staphylococcus arlettae*, *Staphylococcus saprophyticus*, *Staphylococcus warneri*, *Streptococcus mitis*, *Streptococcus parasanguinis* (efficacy for these organisms was studied in fewer than 10 infections); *Propionibacterium acnes*; *Staphylococcus aureus*; *Staphylococcus capitis*; *Staphylococcus epidermidis*; *Staphylococcus haemolyticus*; *Staphylococcus hominis*; *Streptococcus pneumoniae*; *Streptococcus* viridans group.

   Aerobic gram-negative microorganisms: *Acinetobacter lwoffii*, *Escherichia coli*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae* (efficacy for these organisms was studied in fewer than 10 infections); *Haemophilus influenzae*.

   Other microorganisms: *Chlamydia trachomatis*.

AND

2. Ocular Infection diagnosis should have tried and failed two formulary covered ophthalmic agents (ciprofloxacin, levofloxacin, or ofloxacin)

Approval Time Period: Up to 15 days

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Brand Name	Generic Name
XIFAXAN	rifaximin

CRITERIA FOR COVERAGE/NONCOVERAGE

Xifaxan is a rifamycin antibacterial indicated for the treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in adult and pediatric patients 12 years of age and older, the reduction in risk of overt hepatic encephalopathy recurrence in adults, and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. It is not to be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.

Xifaxan will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Member has a diagnosis of **travelers' diarrhea caused by *E.coli*** and meets ALL of the following:
    a. Member is 12 years of age or older.
    b. Lab documentation supporting *E.coli* infection.
    c. Member does not have fever or blood in the stool.
    d. Member has tried and failed an adequate course of at least one oral antibiotic such as ciprofloxacin, azithromycin or levofloxacin.
    e. Treatment duration for this indication does not exceed 3 days, 200 mg three times a day.

2. Member has a diagnosis **to reduce the risk of recurrent overt hepatic encephalopathy** (HE) and meets ALL of the following:
    a. Member is 18 years of age or older.
    b. Diagnosis supported by documentation of ≥ two episodes of HE in the previous six months that included symptoms of impaired mental status, asterixis, and fatigue.
    c. Member has tried and failed **three** consecutive months of lactulose therapy. Failure defined as **ONE** of the following:
        i. One or more documented episodes of overt HE during the three month trial in which the patient exhibited an increase in symptoms of HE (impaired mental status, asterixis and fatigue).
        ii. An increase in ammonia levels from baseline during the 3 month trial.
    d. Lactulose will be used with Xifaxan as part of the treatment plan.
        - **Note:** *Per the American Association for the Study of Liver Diseases (AASLD), the data does not support the use of Xifaxan alone. Per the Xifaxan prescribing information: "In the trials of Xifaxan for HE, 91% of the patients were using lactulose concomitantly."*
        - ***Note:*** *Not tolerating the taste of lactulose is not considered a failure of lactulose therapy.*
    e. Approval duration for hepatic encephalopathy is 6 months, 550 mg twice daily.

3. Member has a diagnosis of **moderate to severe IBS-D** and meets **ALL** of the following:
    a. Member is 18 years of age or older.
    b. Diagnosis supported by documentation of symptoms of moderate abdominal pain and bloating.
    c. The member has had an adequate documented trial of 30 days and failure of one drug from both of the following drug classes:
        i. Antispasmodic *(e.g. dicyclomine, hyoscyamine).*

ii. Tricyclic antidepressant *(e.g. amitriptyline, nortriptyline, imipramine, or clomipramine).*

d. Documentation that dietary modification has been tried (e.g., low carbohydrate diet, lactose free diet if lactose intolerant, etc.).

e. Approval duration for IBS-D is a max of 3 treatment courses of 550mg three times daily x 14 days = 42 days total (126 tabs). A 14 day course treatment may be repeated up to two times for recurrence of symptoms.

Continuation for coverage criteria:

Hepatic Encephalopathy

1. Member has a documented continued stable decrease in symptoms (impaired mental status, asterixis and fatigue) or a continued stable decrease in ammonia levels from baseline.
2. Member has continued and adherent use of lactulose with Xifaxan verified per prescription claim history.

Exclusions for coverage: Member has a hypersensitivity to rifaximin, any component of the product, or other rifamycin antimicrobial agents.

References:

1. Vilstrup, H, Amodio, P, et al. AASLD Practice Guideline: Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver.
2. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 7/2017.
3. Facts& Comparisons Answers at http://online.factsandcomparisons.com.Accessed 7/2017.
4. Centers for Disease Control and Prevention. CDC Health Information for International Travel 2016. New York: Oxford University Press; 2016. Chapter 2, Table 2-06.
5. Ford AC, Moayyedi, P, et al. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. *Am J Gastroenterol* 2014;109:S2-S26;doi:10.1038/ajg.2014.

Criteria Revised: 9/2017

Brand Name	Generic Name
ZIOPTAN	Tafluprost

CRITERIA FOR COVERAGE/NONCOVERAGE

Zioptan (tafluprost) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

- Elevated intraocular pressure (IOP): for the reduction of elevated IOP in patients with open-angle glaucoma and ocular hypertension.

AND

- Member must try and fail formulary medications latanoprost, and travaprost.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

This guideline will be reviewed on an annual basis.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered products	Brand or generic Name
zolpidem ER	AMBIEN CR
zolpidem sublingual	INTERMEZZO
EDLUAR	zolpidem sublingual
ZOLPIMIST	zolpidem oral spray

CRITERIA FOR COVERAGE/NONCOVERAGE

Zolpidem ER is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Available in a 6.25mg and 12.5mg dose. Maximum dose per day is 12.5mg.
Zolpidem sublingual is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Not indicated for the treatment of middle-of-the night awakening when a patient has fewer than 4 hours of bedtime remaining before the planned time of waking.
EDLUAR is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Maximum dose per day is 10mg.
ZOLPIMIST is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Maximum dose per day is 10mg.

Note: *Zolpidem has shown modest benefit in helping people sleep. However, it has not been shown in clinical studies to improve health outcomes among people with insomnia.*

Zolpidem ER will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia. Chronic insomnia defined as difficulty initiating or maintaining sleep or early-morning awakening with inability to return to sleep and has occurred for at least **three** nights per week and is present for at least **three** months.
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days of therapy and failure of each of the following at maximum therapeutic doses:
    d.Zolpidem 10mg.
    e.Temazepam 30mg.
    f.Eszopiclone 3mg (prior authorization may be required).

Zolpidem sublingual (generic for Intermezzo) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia. Chronic insomnia defined as difficulty initiating or maintaining sleep or early-morning awakening with inability to return to sleep and has occurred for at least **three** nights per week and is present for at least **three** months.
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days of therapy and failure of each of the following at maximum therapeutic doses:
    a. Zolpidem 10 mg.
    b. Temazepam 30 mg.
    c. Eszopiclone 3 mg (prior authorization may be required).
4. Documentation has been submitted the member is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting that interferes with daily use of non-sublingual dosage forms.

EDLUAR and ZOLPIMIST will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a document diagnosis of insomnia characterized by difficulties with sleep initiation only.
2. The member is over the age of 18 years old.

3. A documented trial of at least 30 days of therapy and failure of each of the following at maximum therapeutic doses:
    a. Zolpidem 10 mg
    b. Temazepam 30 mg
    c. Eszopiclone 3 mg (prior authorization may be required)
    d. Zolpidem ER
    e. Zolpidem sublingual (generic Intermezzo)
4. Documentation has been submitted the member is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting that interferes with daily use of non-sublingual dosage forms.

Quantity limits:
Zolpidem ER – #30 per 30 days
Zolpidem sublingual - #30 per 30 days
EDLUAR - #30 per 30 days
ZOLPIMIST – One 7.7ml bottle (60 metered actuations) per 30 days

Approval Length:
Zolpidem ER – 12 months
Zolpidem sublingual – 12 months
EDLUAR – 3 months
ZOLPIMIST – 3 months

Medication	Recommended Dosing per Night	
	Men	Women
zolpidem ER	6.25 – 12.5 mg	6.25 mg
zolpidem sublingual	3.5 mg	1.75 mg
Edluar	5-10 mg	5 mg
Zolpimist	5-10 mg	5 mg

Exclusions:
1. Use concurrently with other formulations of zolpidem.
2. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate).

References:

1. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;12(2):307-349.
2. Zolpimist full prescribing information. ECR Pharmaceuticals. Richmond, Virginia.
3. Edluar full prescribing information. Somerset, NJ. Meda Pharmaceuticals Inc.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
5. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 9/9/17.

Criteria created 9/2017

Brand Name	Generic Name
ZORTRESS	Everolimus

CRITERIA FOR COVERAGE/NONCOVERAGE

ZORTRESS® (everolimus) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The patient is 18 years of age or older

2. The prescriber is experienced in immunosuppressive therapy and management of transplant patients.

3. Member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:
    A. The medication is being used for prevention of kidney transplant organ rejection and member meets both criteria (i) and (ii) below:
        i. The member is at low-to-moderate immunologic risk
        ii. The member is prescribed concurrent therapy with reduced doses of cyclosporine and corticosteroids

    B. The medication is being used for prevention of liver transplant organ rejection and member meets both criteria (i) and (ii) below:
        i. Thirty (30) or more days have passed since the transplant procedure
        ii. The member is prescribed concurrent therapy with reduced doses of tacrolimus and corticosteroids

Authorization will be approved for lifetime.

References
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Covered Products	Generic Name
ZYVOX oral suspension	Linezolid
Linezolid oral tablet	

CRITERIA FOR COVERAGE/NONCOVERAGE (HC)

Zyvox (linezolid) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

- Community-acquired pneumonia: caused by Streptococcus pneumonia (including multi-drug resistant strains), including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptable strains only).
- Complicated skin and skin structure infections: complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by S. aureus, (methicillin-susceptible and resistant strains), Streptococcus pyogenes, or Streptococcus agalactiae.
- Nosocomial pneumonia: caused by S. aureus (methicillin-susceptible and resistant strains), or S. pneumonia (including multi-drug-resistant strains).
- Uncomplicated skin and skin structure infections: Caused by *S. aureus* (methicillin- susceptible strains only) or *S. pyogenes*
- Vancomycin-resistant enterococcal infections: Vancomycin-resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia

AND

- Current Culture and Sensitivity (C&S) in support of FDA indication

Authorization will be for duration of therapy not to exceed 28 days of therapy (including doses given in hospital, emergency room, or urgent care). Additional course of therapy will require new PA submission and clinical notes documenting response and need for additional therapy.

References
Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 11/2016
Criteria last reviewed and updated: 11/2016

Criterianame	
COMPOUNDS	

CRITERIA FOR COVERAGE/NONCOVERAGE

Compounds will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Prescribed by a valid provider for the treatment of an FDA-approved indication, or clinically accepted indication supported by medical literature;

AND

- Is Medically Necessary;

AND

- The route of administration or method of delivery is supported by medical literature;

AND

- Requested compound product is not commercially available due to:
- No comparable commercially available product (i.e. dosage form or route of administration);

OR

- Market withdrawal due to economic concerns, not safety;

OR

- Manufacturer shortage of commercial product with no estimated availability date;

AND

- Patient is unable to use commercially available product due to:
- Hypersensitivity to any of the components (i.e. dyes, preservatives or fragrances);

OR

- Physical disability that would prevent the use of commercially available product (i.e. inability to swallow, etc.);

OR

- Contraindication to any of the components (i.e. drug interaction, etc.);

AND

- Ingredients used are required due to:
- All ingredients are supported by medical literature for the stability and efficacy of the compound;

OR

- Use of a high cost ingredient where less costly alternatives are available (i.e. proprietary bases, etc.) is supported by medical literature for the stability and efficacy of the compound (provide supporting documentation);

AND

- Prior authorization requirements for specific active ingredients have been met, if applicable

Plan will not approve coverage of prescription compounds in the following instances:

- Compound ingredients exceed FDA approved maximum dosing
- Compound contains only over-the-counter ingredients
- Compound contains only non-active ingredients
- Compound contains non-covered bulk chemical products
- Compound contains Plan excluded product(s)
- Compound is used for the treatment of Plan excluded indications
- Supporting documentation is not provided (i.e. chart notes, clinical trials, etc.

Approval will be granted for 12 months unless shorter duration requested by prescriber.

Criteria last reviewed 11/2016

Criteria Name
Non Formulary and Quantity Limit

CRITERIA FOR COVERAGE/NONCOVERAGE

Non formulary drugs and requests for exceeding quantity limits on certain drugs will be considered for coverage under the pharmacy benefit program when all of following criteria are met:

1. **Drug (and prescription) must be prescribed by a Health Choice contracted provider.**

2. **Documented trial and failure of ALL available formulary and preferred alternatives** in a specific drug class unless contraindication exists or previous established intolerance that is documented by the prescriber. Documentation must include dates of trial and failure in the chart notes and supported by prescription claims history.

3. **If all formulary and preferred alternatives in a specific drug class have been tried and failed or established documented intolerance or contraindication exists then the requested medication and the diagnosis must meet either a, b, or c listed below**.

   a. **Requested medication and the diagnosis must meet the FDA indication in full.**
   In full defined as indication, drug strength, directions, dosing modifications, warnings, contraindications, any black box warnings, and any other pertinent clinical information as per the prescribing information. Documentation is required and all of the below must be met:
      i. Recent chart notes that include the treatment plan with the requested non-formulary medication or quantity limit.
      ii. Lab work pertaining to drug as indicated per the FDA prescribing information.
      Example: Hepatic, renal function, or other labs that would affect the approvable quantity if impairment exists.

   b. **Compendia.** If the FDA indication is not met in full then the request is considered off-label and must meet one of the following compendia in full.
      i. American Hospital Formulary Service (AHFS) Compendium.
      ii. Micromedex/DrugDex Compendium with a ***Class I, IIa, or IIb rating.***
      iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a ***strong recommendation.***
      iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and a Strong recommendation.***
      v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) ***Category of 1, 2A, or 2B.***

   c. Evidence. If the FDA indication or compendia is not met then **two** published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug and/or quantity with the diagnosis can be submitted for review.
   The clinical trials must be consistent with the drug requested including the dosing. The conclusion by the trial authors must include it is considered safe and effective for the requested use.

Clinical Trial Phases:

- **Preclinical research:** A trial done in a lab and not tested in animals or humans.
- **Phase 0:** The first clinical trials to be done among people. In these trials a very small dose of a drug is given to about 10 to 15 people.

- **Phase I**: An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects.
- **Phase II**: An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete.
- **Phase III**: Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way.
- **Phase IV**: After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment's risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials.

Approval length: Up to 12 months.

Continuation criteria:

1. Chart notes documenting a positive response to therapy and no intolerable side effects. Labs may be required to support response to therapy if indicated per the prescribing information.

References:

1. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
3. American Society of Clinical Oncology (ASCO). ASCO Guidelines, Tools, & Resources. 2017.
4. Facts & Comparisons Answers. Available at: http://online.factsandcomparisons.com Accessed 7/2017.
5. Micromedex/DRUGDEX. Available at: www.microdexsolutions.com Accessed 7/2017.
6. Arizona Health Care Cost Containment System. AHCCCS Medical Policy Manual. Policy 310-V Prescription Medications/Pharmacy Services. Rev 2/1/2017.

Criteria revised 9/2017

Criteria Name
Non Formulary and Quantity Limit Opioids

CRITERIA FOR COVERAGE/NONCOVERAGE

Non Formulary and Quantity limit Opioids will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Required information and documentation for all Opioids (Schedule C2 and C3) must be submitted by the prescriber with the authorization request:

1. Documented comprehensive medical and pain related evaluation that includes the member's medication history, trial and failures of non-opioid medications
2. Specialist assessment of pain related diagnosis (orthopedics, neurologist, rheumatologist, gastroenterologist, oncologist and pain management specialist)
3. The prescriber has educated the member on the potential side effects of using narcotic analgesics, including the risk for misuse, abuse and addiction related to continuing on opioid therapy
4. The member has been screened for behaviors indicative of a developing substance abuse disorder including but not limited to abuse/misuse of current prescriptions
5. The prescriber has reviewed the member's profile in the AZ CSPMP (Controlled Substances Prescription Monitoring Program) within the last 30 days from the date of the request
    a. Oncologists who are prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to review the member's CSPMP profile
6. Documentation of a random drug screen within the past 4 months from the date of the request (unless member is under Hospice care or at end of life).
7. The prescriber must provide chart notes or other evidence that coordination of care is present IF:
    a. The prescriber is not the primary care physician (need evidence of coordination of care w/ PCP)
    b. The patient is being treated by a behavioral health provider and prescriber is not the BH provider (need evidence of coordination of care w/ BH provider)
    c. If the patient is in a substance abuse treatment program, there must be a patient signed medical release to share information between providers

Coverage Guidelines for medical necessity (formulary exception):

- Member indication/diagnosis consistent with FDA approved uses
    - Resources include: Facts & Comparisons eAnswers, American Hospital Formulary Service Drug Information (AHFS), United Sated Pharmacopeia Drug Information (USP-DI), and/or MICROMEDEX- DRUGDEX Offlabel use needs to be reviewed by appropriate clinical staff (pharmacist or physician or nurse)
- No contraindications to drug (per F&C or other specified drug references above) are present within member information
- Documented member trial and failure and/or contraindications of three formulary products.
- Certain opioids will require the member to be considered as opioid tolerant (members who have been taking, for 1 week or longer, morphine 60 mg/day or more, fentanyl transdermal 25 mcg/h or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, oral oxymorphone 25 mg/day or more, or an equianalgesic dose of another opioid.
- If member is new to drug therapy, the need for greater than an initial 7 day supply will be need to be addressed (Refer to criteria for "Short Acting Opioid Therapy Exceeding a 7 Day Supply")

Coverage Guidelines for exceeding established Quantity Limit (formulary) – must meet (1), (2) and (3):

1. The maximal doses specified under the quantity restriction has been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

    a. If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

2. There is documented clinical rationale for the requested dosage, quantity, or duration of medication

3. Given the known relevant physical or mental characteristics of the member and known characteristics of the drug regimen, the requested dosage, quantity, or duration is safe and effective based on sound clinical evidence and medical and scientific evidence contained in peer-reviewed medical literature, accepted Standards of medical practice, and/or one of the following Compendia:
    a. American Hospital Formulary Service (AHFS) Compendium
    b. Micromedex/DrugDex (not Drug Points) Compendium
    c. Elsevier Gold Standard's Clinical Pharmacology Compendium
    d. National Comprehensive Cancer Network Drugs and Biologics Compendium

Approval Time Period: 6 months

**For patients under the age of 18, prescriptions for all opioid medications (long and short acting) will be limited to a 7 day supply except in the case of cancer, other chronic disease, or traumatic injury.

1. For diagnosis of cancer or other chronic disease, approval duration will be for 6 months.
2. For traumatic injury, approval duration will be for the requested duration or up to a maximum of 3 months.
3. Refer to criteria “Short Acting Opioid Therapy Exceeding a 7 Day Supply”

References
CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
Arizona Opioid Prescribing Guidelines, November 2014. http://www.azdhs.gov
www.micromedexsolutions.com Accessed 11/2016
http://eanswers.factsandcomparisons.com/index.aspx Accessed 11/2016
Criteria updated 11/2016

Criteria Name
Antidepressants in Children < 6 years old

CRITERIA FOR COVERAGE/NONCOVERAGE

Antidepressants will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

- The requesting clinician has documented that the child has a diagnosis of major depressive disorder (MDD).
- Psychosocial issues and non-medical interventions are being addressed by the clinical team.
- Documentation of psychotherapeutic intervention (e.g., Dyadic therapy) occurring for at least 6 to 9 months before requesting antidepressant therapy.
    - Documentation provided includes interventions tried, date and duration of trial, and why interventions were unsuccessful.
- Prescribed by or in consultation with a child psychiatrist.
- Prescriber attests to monitoring child in accordance with the ADHS/DBHS Clinical Practice Protocol on Psychiatric Best Practice Guidelines for Children: Birth to Five Years of Age.

Coverage is not authorized for:

- Indications other than MDD.
- Doses greater than FDA recommended maximum daily dosage for pediatrics unless accompanied with supporting documentation.
- The use of antidepressants without psychosocial treatment.

Authorization for continued use shall be reviewed at least every 3 months to confirm medical necessity and lack of contraindications to continued therapy.

References:
ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
AHCCCS Toolkit for the Management of Childhood and Adolescent Depression. https://www.azahcccs.gov. Accessed 10/2016
Overview of treatment for pediatric depression. www.uptodate.com Accessed 10/2016

Criteria Name
ADHD Medications in Children < 6 years old

CRITERIA FOR COVERAGE/NONCOVERAGE

ADHD medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The requesting clinician has documented that the child has a diagnosis of ADHD.
2. Psychosocial issues and non-medical interventions are being addressed by the clinical team.
3. Documentation of psychosocial evaluation occurring before request for ADHD medications.
    a. Documentation provided includes of date of evaluation and name of clinician conducting assessment.
4. Documentation of non-medication alternatives that have been attempted before request for ADHD medications.
    a. Documentation provided includes interventions tried, date and duration of trial and why interventions were unsuccessful.
5. If dose is greater than FDA approved maximum daily dose, provide details and supporting documentation.
6. Prescriber attests to monitoring child in accordance with the ADHS/DBHS Clinical Practice Protocol on Psychiatric Best Practice Guidelines for Children: Birth to Five Years of Age.
7. Prescribed by or in consultation with a child psychiatrist.

Coverage is Not Authorized for:

1. Indications other than ADHD.
2. Doses greater than FDA recommended maximum daily dosage unless accompanied with supporting documentation.

Authorization for continued use shall be reviewed at least every 3 months to confirm medical necessity and lack of contraindications to continued therapy.

References:
ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
Manufacturer Product Information
Pliska SR, Greenhill LL, Crismon ML, et al. The Texas children's medication algorithm project: report of the Texas census conference panel on medication treatment of childhood deficit/hyperactivity disorder. Part 1. J Am Academy Child Adolescent Psychology. 200;39(7):920-927

Criteria Name
Concomitant Long Acting Opioid Therapy
Applies to all long acting opioids (formulary and non-formulary agents)
Formulary products include: Butrans, Embeda, Fentanyl patches, Hyzingla ER, Morphine Sulfate ER tablets and Oxycontin

CRITERIA FOR COVERAGE/NONCOVERAGE

Controlled release opioid agents will be considered for concurrent or concomitant therapy coverage under the pharmacy benefit program when all of the following criteria are met:

1. Indication (diagnosis) for both drugs is consistent with FDA labeling or medical compendia (e.g. DrugDex).
2. Documentation of around the clock pain relief (analgesia) with opioid is present.
3. Medical necessity of concomitant therapy is justified in clinical notes
4. Dosing of both drugs is consistent with clinical literature
5. No contraindications exists if used together
6. Prescriber of the two long acting agents is the same
    a. If prescribers are not the same, each prescriber has been contacted and is aware of use of both drugs together
    b. Prescribers are aware of any short acting opioids (e.g., oxycodone, hydrocodone/APAP)
    c. Prescribers are aware of any other controlled substances. (e.g., benzodiazepines)
7. A current, within 4 months, UDS is included with your request.
8. Documentation of CSPMP review is present in provider clinical notes with any findings.
9. If one drug is going to replace the other (taper on and taper off), the duration of use together is limited to less than 30 days. If yes, approve for 30 days. Taper dosing for changing to a different CR Opioid must be noted in the chart notes or pharmacist case notes with taper schedule included.

Authorization for continued use shall be reviewed at least every 6 months to confirm medical necessity and lack of contraindications to concomitant therapy.

References:
Micromedex/DRUGDEX at www.microdexsolutions.com
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com.

Criteria Name
Concomitant Anxiolytic Therapy -- Applies to all anxiolytics (formulary and non-formulary agents)
Formulary products include: alprazolam, buspirone, chlordiazepoxide, clorazepate, diazepam, lorazepam and oxazepam

CRITERIA FOR COVERAGE/NONCOVERAGE

Anxiolytic agents will be considered for concurrent or concomitant therapy coverage under the pharmacy benefit program when the following criteria are met:

- Indication (diagnosis) for both drugs is consistent with FDA labeling or medical compendia (e.g. DrugDex)

AND

- Medical necessity of concomitant therapy is justified in clinical notes

AND

- Dosing of both drugs is consistent with clinical literature

AND

- No contraindications exists if used together

AND

- Prescriber of the two drugs is the same
  OR
- If prescribers are not the same, each prescriber has been contacted and is aware of use of both drugs together

AND

- Documentation of CSPMP review is present in provider clinical notes or pharmacist reviewer case notes as deemed applicable by pharmacist. Review references safe and monitored use of agents concomitantly considering members current medication profile

AND

- If one drug is going to replace the other (taper on and taper off), the duration of use together is limited to less than 60 days. If yes, approve for 60 days or less. Taper dosing for changing to a different anxiolytic must be noted in the chart notes or pharmacist case notes with taper schedule included.

Authorization for continued use shall be reviewed at least every 12 months to confirm medical necessity and lack of contraindications to concomitant therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com.
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com.

Criteria Name
Concomitant Sedative Hypnotic Therapy
Applies to all Sedative Hypnotics (formulary and non-formulary agents)
Formulary products include: estazolam, flurazepam, temazepam, triazolam, zaleplon and zolpidem

CRITERIA FOR COVERAGE/NONCOVERAGE

Sedative hypnotic agents will be considered for concurrent or concomitant therapy coverage under the pharmacy benefit program when the following criteria are met:

- Indication (diagnosis) for both drugs is consistent with FDA labeling or medical compendia (e.g. DrugDex)

AND

- Medical necessity of concomitant therapy is justified in clinical notes

AND

- Dosing of both drugs is consistent with clinical literature

AND

- No contraindications exists if used together

AND

- Prescriber of the two drugs is the same
  OR
- If prescribers are not the same, each prescriber has been contacted and is aware of use of both drugs together

AND

- Documentation of CSPMP review is present in provider clinical notes or pharmacist reviewer case notes as deemed applicable by pharmacist. Review references safe and monitored use of agents concomitantly considering members current medication profile

AND

- If one drug is going to replace the other (taper on and taper off), the duration of use together is limited to less than 60 days. If yes, approve for 60 days or less. Taper dosing for changing to a different hypnotic must be noted in the chart notes or pharmacist case notes with taper schedule included.

Authorization for continued use shall be reviewed at least every 12 months to confirm medical necessity and lack of contraindications to concomitant therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com.
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com.

Criteria Name
Concomitant Short Acting Opioid Therapy
Applies to all Short Acting Analgesics and Opioids (formulary and non-formulary agents)

CRITERIA FOR COVERAGE/NONCOVERAGE

Short Acting (IR Formulations) Opioids will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Concurrent therapy
Review of the CSPMP is documented in chart notes.
AND
A current, within 4 months, UDS is included with your request
AND
Documentation of medical necessity for concurrent therapy.
AND
No more than two prescriptions for **two medications** per 30 days
OR

If taper dosing is needed for moving to a different Immediate Release Opioid it must be noted in the chart notes with taper schedule and duration included.

Authorization for continued use shall be reviewed at least every 6 months to confirm there are no contraindications to therapy.

References
Micromedex/DRUGDEX at www.microdexsolutions.com.
Facts & Comparisons eAnswers at http://online.factsandcomparisons.com.

Criteria Name
Short Acting Opioid Therapy Exceeding a 7 Day Supply
Applies to all short acting opioids (formulary and non-formulary agents)

CRITERIA FOR COVERAGE/NONCOVERAGE

Short acting opioid therapy exceeding a 7 day supply will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

D. If the member meets one of the following conditions as outlined in AHCCCS AMPM Policy 310-V, Exhibit 310-V-2, the request may be approved for the appropriate duration of therapy with a maximum duration of 6 months:
   1. The member has a diagnosis of neoplasm related pain (ICD-10 code G89.3).
   2. The member is enrolled in Hospice Care.
   3. The use of the short-acting opioid is for "end-of-life care" (other than hospice).
   4. The use of the short-acting opioid is for palliative care.
   5. The use of the short-acting opioid is for a child on opioid wean at the time of hospital discharge.
   6. The use of the short-acting opioid is for a traumatic injury, excluding post-surgical procedures, as outlined in AHCCCS AMPM Policy 310-V, Exhibit 310-V-3.
   7. The use of the short-acting opioid is for a post-surgical procedure. Up to 14 day supply is approvable per AHCCCS AMPM policy 310-V, however greater than 14 day supply requires clinical review.

E. For other conditions of acute or chronic pain not mentioned above, the following information and documentation is required:
   1. Documented comprehensive medical and pain related evaluation
   2. The member has a documented trial and failure of non-pharmacologic treatment
   3. The member has a documented trial and failure of non-opioid medications (e.g. topical NSAIDs, analgesics or anesthetics, and oral NSAIDs and muscle relaxants)
   4. The prescriber has included the estimated duration of therapy and the treatment plan
   5. The prescriber has educated the member on the potential side effects of using narcotic analgesics, including the risk for misuse, abuse and addiction related to continuing on opioid therapy
   6. The member has been assessed for behaviors indicative of a developing substance abuse disorder including but not limited to abuse/misuse of current prescriptions
   7. The prescriber has reviewed the member's profile in the AZ CSPMP (Controlled Substances Prescription Monitoring Program) within the last 30 days from the date of the request
      a. Oncologists who are prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to review the member's CSPMP profile
   8. UDS may be required by clinical reviewer on case specific basis

F. The prescriber must provide chart notes or other evidence that coordination of care is present IF:
   1. The prescriber is not the primary care physician (need evidence of coordination of care w/ PCP)
   2. The patient is being treated by a behavioral health provider and prescriber is not the BH provider (need evidence of coordination of care w/ BH provider)
      (If the patient is in a substance abuse treatment program, there must be a patient signed medical release to share information between providers)

Duration of approval: Duration requested by provider with a maximum of 6 months.

References:

7. AHCCCS AMPM Chapter 300, Policy 310-V and Chapter 900, Policy 960.
8. Arizona Opioid Prescribing Guidelines, November 2014. http://www.azdhs.gov
9. http://www.azleg.gov/ars/36/02606.htm

Criteria updated 03/2017

PHARMACY Medication Prior Authorization Request Form

FAX: (877) 422-8130 Phone: (800) 322-8670

To ensure a timely response, please fill out the form completely and legibly.

A decision will be rendered within 24 hours of receipt of the request if all the required information is present.
If the request lacks sufficient information to render a decision, the prescriber with be notified of the required information within 24 hours of receipt of the request, and a decision will be rendered within seven (7) days from the initial date of the request.

Member Name Last, First)	Member ID#	DOB	Date
Requesting Provider Name	NPI:	PCP (if different)	
Office Contact Person	Direct Phone #	Fax #	
Diagnosis 1 (include ICD-10)	Diagnosis 2	Diagnosis 3	

Please send all pertinent clinical documentation with this fax.

Use of pharmaceutical samples cannot be accepted as justification.

Name of Medication	Dosage	Quantity/ Amount	Refills (<12)
Sig/Instructions	Allergies		
List Formulary Medications Tried. Include dates of treatment and response to treatment of each drug.			
List Formulary Medications Contraindicated / Reason			

☐ Continuation of therapy. Recent clinical documentation of response to medication and other clinical evidence supporting continuation of therapy is required.

 Date Revised: October 2017