Abilify Maintena (aripiprazole extended release suspension)

Covered uses	All medically accepted indications
Exclusion Criteria	Abilify Maintena should be avoided in populations with dementia-related psychosis. (Black Box warning)
Required Medical Information	1. Medical diagnosis of Schizophrenia or Bipolar I disorder 2. Must have failed at least 2 weeks of 2 oral atypical antipsychotics (aripiprazole, risperidone, paliperidone, ziprasidone, quetiapine, olanzapine, etc.) **OR** provide documentation of non-compliance, inability to swallow oral medications, or contraindication to oral atypical antipsychotics. 3. Requested maintenance dose is administered once monthly
Age restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Members currently taking this medication at the time of enrollment will not be required to meet prerequisites for authorization The recommended starting and maintenance dose of Abilify Maintena is 400 mg monthly (no sooner than 26 days after the previous injection).

References:

- Abilify Maintena (Aripiprazole). National Library of Medicine and National Institutes of Health. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ee49f3b1-1650-47ff-9fb1-ea53fe0b92b6#S2.5. Updated February 23, 2017. Accessed August 8, 2017.

Zytiga (abiraterone acetate)

Covered uses	All medically accepted indications
Exclusion Criteria	Pregnancy
Required Medical Information	1. Medical diagnosis of metastatic castration-resistant prostate cancer. 2. Zytiga must be administered in combination with prednisone 3. Requested dose is 1,000 mg (four 250 mg tablets) once daily in combination with prednisone 5 mg twice daily.
Age restrictions	18 years or older
Prescriber Restrictions	Oncologist Urologist
Coverage Duration	1 year
Other Criteria	Members currently taking this medication at the time of enrollment will not be required to meet prerequisites for authorization

References:

1) Zytiga [package insert]. Janssen Biotech, Inc. Horsham, PA. May 2016

Applies to:
Nebraska Family Planning (CHP599)

Albenza (albendazole)

Covered uses	All medically accepted indications
Exclusion Criteria	See age restrictions
Required Medical Information	Enterobiasis, ascariasis: Medical documentation indicating use for treatment for enterobiasis and previous trial and failure to ivermectin and Pin-X Intestinal strongyloidiasis, cutaneous larva migrans, or infection by loa loa: Medical documentation indicating use for treatment for intestinal strongyloidiasis, cutaneous larva migrans, or infection by loa loa and previous trial and failure to ivermectin. Approve for use as empiric treatment for presumptive strongyloides infection in Sub-Saharan Africa refugees from LoaLoa endemic countries, regardless of previous ivermectin use.[2] Echinococcosis (Hydatid disease), neurocysticercosis: Medical documentation indicating the use for treatment of echinococcosis or neurocysticercosis.
Age restrictions	1 year of age or older
Prescriber Restrictions	None
Coverage Duration	6 months (Hytadid) 1 month for other indications
Other Criteria	None

Reference

1. Albenza [package insert]. Amedra Pharmaceuticals. Horsham, PA. February, 2013
2. Centers for Disease Control and Prevention. Guidelines for Overseas Presumptive Treatment of Strongyloidiasis, Schistosomiasis, and Soil-Transmitted Helminth Infections. http://www.cdc.gov/immigrantrefugeehealth/guidelines/overseas/intestinalparasites-overseas.html. Accessed August 20, 2014.

Applies to:
Nebraska Family Planning (CHP599)

LUMIZYME®, MYOZYME® (alglucosidase alfa)

Covered uses	All medically accepted indications
Exclusion Criteria	N/A
Required Medical Information	• Diagnosis of acid alpha-glucosidase deficiency (Pompe disease)
Age restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Max 20 mg/kg/dose IV. The dose is administered once every 2 weeks

Reference

Lumizyme [package insert]. Genzyme Corporation. Cambridge, MA. August 2014

Applies to:
Nebraska Family Planning (CHP599)

Makena (17 alpha-hydroxyprogesterone)

Covered uses	All medically accepted indications
Exclusion Criteria	<16 years of age >50 years of age Do not use Makena in women with any of the following conditions: • 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
Required Medical Information	Statement of need for preterm delivery prophylaxis in females with a singleton pregnancy who have a history of singleton spontaneous preterm birth: 1. Must be continued weekly until week 37 or delivery **AND** 2. Must be initiated between week 16 and week 27 of pregnancy
Age restrictions	Women between 16 and 50 years of age
Prescriber Restrictions	Obstetrician
Coverage Duration	Up to 21 weeks
Other Criteria	Max Dose 250mg weekly Makena is not intended for use in women with multiple gestations

References:

1. Makena [package insert]. Chesterfield, MO: Ther-Rx Corporation; February 2014.
2. How H, Barton J, Istwan N, Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age ast initiation of treatment matter? American Journal of Obstetrics and Gynecology. 2007 September.

3. Rebarber A, Roman A, Fox N, Recurrent Preterm Birth Prevention in Women Receiving Prophylactic 17P Experiencing Symptoms of Preterm Labor. Presented at 32nd Annual meeting of the Society for Maternal-Fetal Medicine, Dallas, Texas. February 2012.
4. Gonzalez-Quintero V, Istwan N, Rhea D, Gestational Age at Initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. J Matern Fetal Neonatal Med. 2007 Mar; 20(3): 249-52.

Applies to:
Nebraska Family Planning (CHP599)

Letairis (ambrisentan)

Covered uses	All FDA Approved Indications
Exclusion Criteria	Pregnancy Pulmonary Hypertension • World Health Organization group 2 - 5
Required Medical Information	Documented diagnosis of: Pulmonary Arterial Hypertension (Idiopathic, inherited, due to drugs/toxins, connective tissue diseases, etc.) World Health Organization Group 1 with predominately NYHA class II or III symptoms: • To improve exercise ability and delay clinical worsening. • In combination with tadalafil to reduce risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.
Age restrictions	Age 18 years or greater
Prescriber Restrictions	Cardiologist or Pulmonologist
Coverage Duration	1 year
Other Criteria	N/A

References:

1. Letaitis [package insert]. Gilead Science. Foster City, CA. October 2015
2. N. Galie, J.A. Barbera, A.E. Frost, *et al.*Initial Use of Ambrisentan plus Tadalafil in Pulmonary Arterial Hypertension. N. Engl. J. Med., 373 (2015), pp. 834–844

Anti-TNF Biologic Products
Enbrel (etanercept), Humira (adalimumab), Cimzia (cetolizumab pegol), Simponi (golimumab), Simponi Aria (golimumab), Remicade (infliximab)

Covered uses	**A. FDA Approved Indications** **1. Ankylosing spondylitis** Enbrel and Humira are indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. Simponi is indicated as monotherapy for patients 18 years or older for reducing signs and symptoms of active ankylosing spondylitis Remicade is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. Cimzia is indicated for the treatment of adults with active ankylosing spondylitis. Humira is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis **2. Plaque psoriasis** Enbrel is indicated for treatment of adult patients 18 years of age and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Adalimumab should only be administered to patients who will be closely monitored and have regular follow-up visits with a health care provider. Remicade is indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. **3. Polyarticular juvenile idiopathic arthritis** Enbrel is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Humira is indicated for reducing signs and symptoms in

	patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis alone or in combination with methotrexate. **4. Psoriatic arthritis (PsA)** Enbrel is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Etanercept can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. Humira is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis alone or in combination with disease-modifying antirheumatic drugs (DMARDs). Simponi is indicated as monotherapy or as adjunct therapy for the treatment of active arthritis in patients age 18 or older with psoriatic arthritis PsA). Cimzia is indicated for the treatment of adult patients with active psoriatic arthritis (PsA). Remicade is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. **5. Rheumatoid arthritis (RA)** Enbrel is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA. Etanercept can be initiated in combination with methotrexate or used alone. Humira is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) alone or in combination with methotrexate or other DMARDs. Cimzia is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA). Simponi and Simponi Aria are indicated as adjunct therapy for the

	treatment of moderately to severely active rheumatoid arthritis (RA). Remicade, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. **6. Crohn's Disease** Humira is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab. Cimzia is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. Remicade is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. **7. Ulcerative Colitis** Remicade is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. Simponi is indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for: • inducing and maintaining clinical response • improving endoscopic appearance of the mucosa during induction • inducing clinical remission • achieving and sustaining clinical remission in induction

	responders Humira is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers **8. Hidradenitis suppurativa** Humira is indicated for the treatment of moderate to severe hidradenitis suppurativa. **9. Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients. **Off-labeled Use:** Drug therapies must be utilized in accordance with FDA approved indications OR the uses found within the compendia of literature† AND the drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program. Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the WellCare Pharmacy and Therapeutics Committee will be predicated on the appropriateness of treatment, scientific evidence and full consideration of medical necessity. †-compendia of current literature: • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex
Exclusion Criteria	TNF- Alpha Inhibitor combination therapy is considered experimental and will not be approved. Positive TB test
Required Medical Information	**A. Rheumatoid Arthritis** a. **Humira,** will be approved based on **all** of the following criteria: (1) Diagnosis of moderate to severe active RA **-AND-** (2) Patient is ≥18 years old **-AND** (3) Prescribed or recommended by a rheumatologist, or immunologist **-AND** (4) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to methotrexate and at least

	one other DMARD [eg, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, cyclosporine] **-AND** (5) Screen for TB b. **Cimzia**, or **Enbrel** will be approved based on **all** of the following criteria: (1) Diagnosis of moderate to severe active RA **-AND-** (2) Patient is ≥18 years old **-AND-** (3) Prescribed or recommended by a rheumatologist or immunologist **-AND-** (4) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to methotrexate and at least **one other** DMARD [eg, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, cyclosporine] **-AND-** (5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to preferred Humira or Simponi **-AND-** (6) Screen for TB c. **Simponi** will be approved based on **all** of the following criteria: (1) Diagnosis of moderate to severe active RA **-AND-** (2) Patient is ≥18 years old **-AND** (3) Prescribed or recommended by a rheumatologist or immunologist **-AND** (4) In combination with methotrexate **-AND** (5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to at least **one other** DMARD [eg, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, cyclosporine] **-AND** (6) Screen for TB d. **Remicade** will be approved based on **all** of the following criteria: (1) Diagnosis of moderate to severe active RA **-AND-**

(2) Patient is ≥18 years old

-AND

(3) Prescribed or recommended by a rheumatologist or immunologist

-AND

(4) In combination with methotrexate

-AND

(5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to at least **one other** DMARD [eg, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, cyclosporine]

-AND

(6) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to preferred Humira or Simponi

(7) Screen for TB

c. **Simponi Aria** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe active RA

-AND-

(2) Patient is ≥18 years old

-AND

(3) Prescribed or recommended by a rheumatologist or immunologist

-AND

(4) In combination with methotrexate

-AND

(5) Trial and failure of Simponi

-AND

(6) Screen for TB

B. Polyarticular Juvenile Idiopathic Arthritis

a. **Enbrel** or **Humira** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severely active polyarticular JIA

-AND-

(2) The patient's age is 2 years or older

-AND-

(3) Prescribed or recommended by a rheumatologist or immunologist

-AND

(4) History of failure (defined as inadequate response or return of symptoms) to **one** of the following:

(a) Non-steroidal anti-inflammatory drugs (**NSAIDs**) [eg, Motrin (ibuprofen), Naprosyn (naproxen)]
(b) Corticosteroids (eg, prednisone)

-AND-

(5) History of failure for at least 3 months, contraindication, or intolerance to methotrexate (Rheumatrex, Trexall)

C. Psoriatic Arthritis (PsA)

a. **Simponi,** or **Humira** will be approved based on **all** of the following criteria:

(1) Diagnosis of active PsA

-AND-

(2) Patient is ≥18 years old

-AND-

(3) Prescribed or recommended by **one** of the following specialists:

(a) Dermatologist
(b) Rheumatologist
(c) Immunologist

-AND-

(4) History of failure after adequate trial (at least 3 months), contraindication, allergy or intolerance to **one** DMARD [eg, Rheumatrex/Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine)]

-AND-

(5) Screen for TB

b. **Enbrel, Remicade, Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of active PsA

-AND-

(2) Patient is ≥18 years old

-AND-

(3) Prescribed or recommended by **one** of the following specialists:

Dermatologist, Rheumatologist, or Immunologist

-AND-

(4) History of failure after adequate trial (at least 3 months), contraindication, allergy or intolerance to **one** DMARD [eg, Rheumatrex/Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine)]

-AND-

(5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to preferred Humira or Simponi

(6) Screen for TB

D. Plaque Psoriasis

a. **Humira** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe chronic plaque psoriasis

-AND-

(2) Patient is ≥ 18 years old

-AND-

(3) History of failure, contraindication, or intolerance to **both** of the following conventional therapies:

(a) Phototherapy with at least **one** of the following, unless unavailable to the patient:

i. Ultraviolet Light B (UVB) used alone or in combination with topical or systemic treatments

ii. Pulsed Dye Laser

iii. Psoralen and exposure to ultraviolet light A (PUVA)

iv. Photochemotherapy

-AND-

(b) Systemic or topical therapy with at least **one** of the following:

i. Methotrexate (Rheumatrex, Trexall)

ii. Cyclosporine (Sandimmune, Neoral, Gengraf)

iii. Topical steroid

iv. Hydroxyurea (Hydrea)

v. Sulfasalazine (Azulfidine)

-AND-

(4) Prescribed or recommended by a dermatologist or immunologist

-AND-

(5) Screen for TB

b. **Enbrel and Remicade** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe chronic plaque psoriasis

-AND-

(2) Patient is ≥ 18 years old

-AND-

(3) History of failure, contraindication, or intolerance to **both** of the following conventional therapies:

(a) Phototherapy with at least **one** of the following, unless unavailable to the patient:

i. Ultraviolet Light B (UVB) used alone or in combination with topical or systemic treatments

ii. Pulsed Dye Laser

iii. Psoralen and exposure to ultraviolet light A

(PUVA)
iv. Photochemotherapy
-AND-
(b) Systemic or topical therapy with at least **one** of the following:
i. Methotrexate (Rheumatrex, Trexall)
ii. Cyclosporine (Sandimmune, Neoral, Gengraf)
iii. Topical steroid
iv. Hydroxyurea (Hydrea)
v. Sulfasalazine (Azulfidine)
-AND-
(4) Prescribed or recommended by a dermatologist or immunologist
-AND-
(5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to preferred Humira
(6) Screen for TB

E. Ankylosing Spondylitis

a. **Humira, or Simponi** will be approved based on **all** of the following criteria:
(1) Diagnosis of ankylosing spondylitis.
-AND-
(2) Patient is ≥ 18 years old
-AND
(3) Prescribed or recommended by a rheumatologist or immunologist
-AND
(4) History of failure (no response after maximum tolerated doses), contraindication, or intolerance to **two or more** NSAIDs [diclofenac, etodolac, ibuprofen, ketoprofen, meloxicam]
-AND
(5) Screen for TB

b. **Cimzia, Remicade, Enbrel** will be approved based on **all** of the following criteria:
(1) Diagnosis of ankylosing spondylitis.
-AND-
(2) Patient is ≥ 18 years old
-AND
(3) Prescribed or recommended by a rheumatologist or immunologist
-AND
(4) History of failure (no response after maximum tolerated doses), contraindication, or intolerance to **two or more** NSAIDs [diclofenac, etodolac, ibuprofen, ketoprofen, meloxicam]

-AND

(5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to preferred Humira or Simponi

(6) Screen for TB

F. Crohn's Disease

a. **Humira,** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe Crohn's disease

-AND

(2) Patient is ≥ 18 years old (≥ 6 years old for pediatric patients)

-AND

(3) History of failure, contraindication, or intolerance to **one or more** of the following conventional therapies:

(a) Corticosteroids (eg, prednisone, methylprednisone, budesonide)

(b) Immunomodulators [eg, 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Methotrexate (Rheumatrex, Trexall)]

(c) Aminosalicylates [eg, Asacol (mesalamine), Azulfidine (sulfasalazine), Dipentum (olsalazine)

-AND-

(4) Prescribed or recommended by a gastroenterologist or immunologist

-AND-

(5) Screen for TB

b. **Cimzia, or Remicade** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe Crohn's disease

-AND

(2) Patient is ≥ 18 years old (≥ 6 years old for pediatric patients-*Remicade only*)

-AND

(3) History of failure, contraindication, or intolerance to **one or more** of the following conventional therapies:

(a) Corticosteroids (eg, prednisone, methylprednisone, budesonide)

(b) Immunomodulators [eg, 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Methotrexate (Rheumatrex, Trexall)]

(c) Aminosalicylates [eg, Asacol (mesalamine), Azulfidine (sulfasalazine), Dipentum (olsalazine)

-AND-

(4) Prescribed or recommended by a gastroenterologist or immunologist

-AND-

(5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to preferred Humira

-AND-

(6) Screen for TB

G. Ulcerative Colitis (UC)

a. **Simponi**, **Humira**, will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe ulcerative colitis

-AND-

(2) Patient is ≥ 18 years old

-AND-

(3) History of failure, contraindication, or intolerance to **one steroid** [corticosteroids (eg, prednisone, methylprednisone, budesonide)], and either sulfasalazine or mesalamine

-AND-

(4) Prescribed or recommended by a gastroenterologist or immunologist

AND-

(5) Screen for TB

b. **Remicade** or will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe ulcerative colitis

-AND-

(2) Patient is ≥ 18 years old

-AND-

(3) History of failure, contraindication, or intolerance to **one steroid** [corticosteroids (eg, prednisone, methylprednisone, budesonide)], **and either** sulfasalazine or mesalamine

-AND-

(4) Prescribed or recommended by a gastroenterologist or immunologist

-AND-

(5) History of failure of adequate trial (at least 3 months), contraindication, or intolerance to preferred Humira or Simponi

-AND-

(6) Screen for TB

H. Hidradenitis suppurativa

a. Humira will be approved based on all the following criteria:

(1) Diagnosis of moderate to severe hidradenitis suppurativa

-AND-

(2) Patient is ≥ 18 years old

-AND-

	(3) Prescribed or recommended by a dermatologist or immunologist **-AND-** (4) For reauthorization, documented reduction of at least 50% in total abscess and inflammatory nodule count **I. Uveitis** a. Humira will be approved based on all the following criteria: (1) Diagnosis of non-infectious intermediate, posterior and panuveitis **-AND-** (2) Patient is ≥ 18 years old **-AND-** (3) Prescribed or recommended by an ophthalmologist **-AND-** (4) Screen for TB and/or active infections, including localized infections **-AND-** (5) Concurrent corticosteroid treatment at Humira treatment initiation **-AND-** (6) For reauthorization, no documented development of new inflammatory chorioretinal and/or inflammatory retinal vascular lesions, an increase in anterior chamber cell grade or vitreous haze grade, or a decrease in best corrected visual acuity
Age Restriction	Diagnosis dependent
Prescriber Restriction	Specialist based on indication
Coverage Duration	12 months for all diagnoses
Other Criteria	Reauthorization for 12 months will be approved for continuation of therapy based on documentation of clinical improvement from ongoing therapy with the requested medication

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29. 2004;63 (Suppl II):ii2-ii12. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases. Ann Rheum Dis. 2011;70(Suppl 1):i2-i36.
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34. Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. Arthritis Rheum. 1993; 36 (6): 729-740.
35. Simponi [package insert]. Janssen Biotech, Inc. Horsham, PA, 2013.
36. Singh JA, Furst DE, Bharat A, et.al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirhuematic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care & Research. Vol.64 No.5, May 2012, pp625-639
37. Remicade [package insert]. Janssen Biotech, Inc. Horsham, PA. November, 2013

Aristada (aripiprazole lauroxil, extended release)

Covered uses	All medically accepted indications
Exclusion Criteria	Aristada should be avoided in populations with dementia-related psychosis. (Black Box warning)
Required Medical Information	1. Medical diagnosis of schizophrenia 2. Must have failed at least 2 weeks of 2 oral atypical antipsychotics (aripiprazole, risperidone, paliperidone, ziprasidone, quetiapine, olanzapine, etc.) **OR** provide documentation of non-compliance, inability to swallow oral medications, or contraindication to oral atypical antipsychotics. 3. Requested dose is administered once monthly, every 6 weeks (882 mg only), or every 8 weeks (1064 mg only).
Age restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Members currently taking this medication at the time of enrollment will not be required to meet prerequisites for authorization

References:

1) Aristada [package insert]. Alkermes, Inc. Waltham, MA. July 2016

Invega Sustenna (paliperidone palmitate)

Covered uses	All medically accepted indications
Exclusion Criteria	Invega Sustenna should be avoided in populations with dementia-related psychosis. (Black Box warning)
Required Medical Information	1. Medical diagnosis of Schizophrenia or Schizoaffective disorder 2. Must have failed at least 2 weeks of 2 oral atypical antipsychotics (aripiprazole, risperidone, paliperidone, ziprasidone, quetiapine, olanzapine, etc.) **OR** provide documentation of non-compliance, inability to swallow oral medications, or contraindication to oral atypical antipsychotics. 3. Requested maintenance dose is administered once monthly
Age restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Members currently taking this medication at the time of enrollment will not be required to meet prerequisites for authorization Dosing for Schizophrenia and Schizoaffective disorder: • The recommended dosing of INVEGA SUSTENNA® for each approved indication is displayed in Table 1:

Table 1: Recommended Dosing of INVEGA SUSTENNA® for Adults with Schizophrenia or Schizoaffective Disorder

Indication	Initiation Dosing (deltoid)		Monthly Maintenance Dose* (deltoid or gluteal)	Maximum Monthly Dose
	Day 1	Day 8		
Schizophrenia	234 mg	156 mg	39–234 mg†	234 mg
Schizoaffective disorder	234 mg	156 mg	78–234 mg‡	234 mg

- *Administered 5 weeks after the first injection.
- † The recommended maintenance dose for treatment of schizophrenia is 117 mg. Some patients may benefit from lower or higher maintenance doses within the additional available strengths (39 mg, 78 mg, 156 mg, and 234 mg).
- ‡ Adjust dose based on tolerability and/or efficacy using available strengths. The 39 mg strength was not studied in the long-term schizoaffective disorder study.

References:

- Invega Sustenna (Paliperidone palmitate). National Library of Medicine and National Institutes of Health. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1af14e42-951d-414d-8564-5d5fce138554. Updated July 14, 2017. Accessed August 8, 2017.
- Lehman AF, Lieberman JA, Dixon LB, McGlashan TH, Miller AL, Perkins DO, Kreyenbuhl J. “Treatment of patients with schizophrenia”. American Psychiatric Association. https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Published February 2004. Accessed July 8, 2017.

Invega Trinza (paliperidone palmitate)

Covered uses	All medically accepted indications
Exclusion Criteria	Invega Trinza should be avoided in populations with dementia-related psychosis. (Black Box warning)
Required Medical Information	1. Medical diagnosis of Schizophrenia 2. Must have failed at least 2 weeks of 2 oral atypical antipsychotics (aripiprazole, risperidone, paliperidone, ziprasidone, quetiapine, olanzapine, etc.) **OR** provide documentation of non-compliance, inability to swallow oral medications, or contraindication to oral atypical antipsychotics 3. Documentation of prior treatment with Invega Sustenna for at least 4 consecutive months 4. Requested maintenance dose is administered once every three months
Age restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Dosing for Schizophrenia: Treatment should be initiated when the next 1-month Invega Sustenna dose is scheduled with an Invega Trinza dose based on the previous 1-month injection dose, using the equivalent 3.5-fold higher dose as shown in Table 1.

Table 1. INVEGA TRINZA® Doses for Adult Patients Adequately Treated with INVEGA SUSTENNA®

If the Last Dose of INVEGA SUSTENNA® is:	Initiate INVEGA TRINZA® at the Following Dose:
78 mg	273 mg
117 mg	410 mg
156 mg	546 mg
234 mg	819 mg

References:

- Invega Trinza (Paliperidone palmitate ER). National Library of Medicine and National Institutes of Health. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c39e65d7-fa44-4e4c-8b12-a654d3ed0eae#S8.1.Updated March 31, 2017. Accessed August 8, 2017.

Applies to:
Nebraska Family Planning (CHP599)

Mepron (atovaquone 750 mg/ 5 mL)

Covered uses	All FDA approved indications
Exclusion Criteria	N/A
Required Medical Information	***Pneumocystis jirovecii* pneumonia (PCP)** 1. **Atovaquone 750 mg/ 5 mL** will be approved based on **all** of the following criteria: a. The patient has a diagnosis (i.e. HIV) warranting PCP infection prophylaxis. **-AND-** b. The patient has a documented intolerance to TMP-SMX *and* dapsone. **-OR** 2. **Atovaquone 750 mg/ 5 mL** will be approved based on **all** of the following criteria: a. The patient has a diagnosis of acute mild to moderate pneumonia caused by *P. jirovecii.* **-AND** b. The patient has a documented intolerance to TMP-SMX.
Age restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

REFERENCES

1 Mepron® Prescribing Information. GlaxoSmithKline, March 2014

2 Centers for Disease Control and Prevention. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. MMWR 2009;58 (No. RR4): 6-10.

3 Atovaquone. Facts and Comparisons. Web. 26 July 2011.

4 El-Sadr WM, Murphy RL, Yurik TM, et al. Atovaquone compared with dapsone for the prevention of *Pneumocystis carinii* pneumonia in patients with HIV infection who cannot tolerate trimethoprim, sulfonamides, or both. N Engl J Med 1998;339:1889-1895.

Applies to:
Nebraska Family Planning (CHP599)

Cabergoline

Covered uses	All FDA approved indications
Exclusion Criteria	Uncontrolled Hypertension Hypersensitivity to ergot derivatives History of cardiac valvular disorders History of pulmonary, pericardial, retroperitoneal fibrotic disorders
Required Medical Information	A. Initial Authorization 1. Cabergoline will be approved based on the following criteria: • Documented diagnosis of hyperprolactinemia (idiopathic or pituitary adenomas) AND • Laboratory results of elevated serum prolactin AND • Confirmation of a cardiovascular evaluation, including an echocardiogram to exclude the presence of valvular disease AND • Statement that patient will be monitored for manifestations of progressive fibrosis throughout treatment B. Reauthorization: 1. Cabergoline will be approved based on the following criteria: • Updated laboratory results of elevated serum prolactin
Age restrictions	18 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial authorization: 3 months Reauthorization: 1 year
Other Criteria	Recommended dosage of cabergoline tablets for initiation of therapy is 0.25 mg twice a week. Dosage may be increased by 0.25 mg twice weekly up to a dosage of 1 mg twice a week according to the patient's serum prolactin level. Dosage increases should not occur more rapidly than every 4 weeks

References:

1) Cabergoline [package insert]. Apotex Corp., Weston, FL. November 2011.

Applies to:
Nebraska Family Planning (CHP599)

Multaq (dronedarone)

Covered uses	All FDA approved indications
Exclusion Criteria	• Patients with PERMANENT atrial fibrillation who will not or cannot be cardioverted to normal sinus rhythm • Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV symptoms • Concomitant use of a strong CYP3A inhibitor • Concomitant use of drugs or herbal products that prolong the QT interval and may induce Torsade de Pointes • Pregnant or nursing • Liver or lung toxicity related to the previous use of amiodarone • Severe hepatic impairment
Required Medical Information	• Diagnosis of one of the following: 1. Paroxysmal atrial fibrillation (AF) 2. Persistent AF defined as AF less than 6 months duration AND • One of the following: 1. Patient is in sinus rhythm 2. Patient is planned to undergo cardioversion to sinus rhythm AND • Patient receiving appropriate antithrombotic therapy AND • One of following: 1. Tried and failed amiodarone 2. Intolerant to or has a hypersensitivity to amiodarone
Age restrictions	Adults ≥18 years old
Prescriber Restrictions	Cardiologist
Coverage Duration	12 months
Other Criteria	N/A

References:

1. Multaq [Prescribing Information]. Sanofi Winthrop Industrie. Ambares, France. March 2014.
2. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2014;64(21):2246-2280

Entecavir

Covered uses	All medically accepted indications
Exclusion Criteria	
Required Medical Information	Criteria for approval: • Must provide statement indicating FDA approved indication of hepatitis B **AND** • Trial and failure of preferred drug
Age restrictions	Age 16 years or greater
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Preferred Drugs: Lamivudine oral tablet 100 mg Entecavir prescribing information contains the following **boxed warning**: Severe acute exacerbations of hepatitis have been reported in patients who have discontinued anti-Hepatitis B therapy including entecavir. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-Hepatitis B therapy. If appropriate, initiation of anti-hepatitis B therapy may be warranted. Entecavir has not been evaluated in HIV/HBV co-infected patients who were not simultaneously receiving effective HIV treatment. Limited clinical experience suggests there is a potential for the development of resistance to HIV nucleoside reverse transcriptase inhibitors if entecavir is used to treat chronic hepatitis B virus infection in patients with HIV infection that is not being treated. Therefore, therapy with entecavir is not recommended for HIV/HBV co-infected patients who are not also receiving HAART. Before initiating entecavir therapy, HIV antibody testing should be offered to all patients. Entecavir has not been studied as a treatment for HIV infection and is not recommended for this use. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogue inhibitors, including entecavir, alone or in combination with antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside inhibitor exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogue inhibitors to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk

	factors. Lactic acidosis with entecavir use has been reported, often in association with hepatic decompensation, other serious medical conditions, or drug exposures. Patients with decompensated liver disease may be at higher risk for lactic acidosis. Treatment with entecavir should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

References:

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb; August 2015
2. Entecavir [package insert.]. Dayton, NJ: Aurobindo Pharma USA, Inc.; April 2016.
3. Terrault NA, Bzowej NH, Chang K-M, Hwang JP, Jonas MM, Murad MH. AASLD guidelines for treatment of chronic hepatitis B. Hepatology 2016;63:261-283.

Erythropoiesis Stimulating Agents (ESA) - Aranesp (darbepoetin alfa), Epogen, Procrit (epoetin alfa)

Covered uses	All medically accepted indications
Exclusion Criteria	• Hgb > 10 g/dL – For **NON-DIALYSIS** associated chronic kidney disease • Hgb > 11 g/dL, For **DIALYSIS** associated chronic kidney disease • Aranesp is not indicated for use: a. In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. b. In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. c. As a substitute for RBC transfusions in patients who require immediate correction of anemia
Required Medical Information	Preferred agent for all diagnoses: **Aranesp** **1.** Documented diagnosis of one of the following indications: a. Anemia due to chronic kidney disease b. Anemia due to chemotherapy in patients with cancer c. Symptomatic anemia in patients with myelodysplastic syndrome (MDS) **2.** Laboratory data within the past 90 days of request a. <u>Anemia due to chronic kidney disease</u> i. **Initial**: Hgb ≤ 10 g/dL (exclude hemoglobin values due to a recent transfusion) **Reauthorization**: Hgb ≤ 10 g/dL or Hgb >10 but ≤ 12 g/dL AND prescriber will reduce or interrupt dose (exclude hemoglobin values due to a recent transfusion) ii. **For non-dialysis CKD**: serum ferritin >100 ng/mL and TSAT > 20% **For dialysis-dependent CKD**: serum ferritin > 200 ng/mL and TSAT > 20% b. <u>Anemia due to chemotherapy in patients with cancer</u> i. At least two months 2 more months of chemotherapy is expected ii. **Initial**: Hgb ≤ 10g/dL (exclude hemoglobin values due to a recent transfusion) iii. **Reauthorization**: Hgb < 12 g/dL (exclude hemoglobin values due to a recent transfusion)

	c. Symptomatic anemia in patients with myelodysplastic syndrome (MDS) i. **Initial**: Erythropoietin level ≤ 500 mU/mL and Hgb ≤ 10 g/dL (exclude hemoglobin values due to a recent transfusion) ii. **Reauthorization**: Hgb ≤ 11 g/dL or Hgb >11 but ≤ 12 g/dL AND prescriber will reduce or interrupt dose (exclude hemoglobin values due to a recent transfusion) d. OTHER INDICATIONS i. Subject to approval with appropriate clinical literature to support safety and efficacy
Age restrictions	N/A
Prescriber Restrictions	• Oncologist or nephrologist (or prescriber in consultation with either specialist)
Coverage Duration	12 weeks
Other Criteria	• Do not increase the dose more frequently than once every 4 weeks. Decreases in dose can occur more frequently. Avoid frequent dose adjustments. • If the hemoglobin rises rapidly (e.g., more than 1 g/dL in any 2-week period), reduce the dose of Aranesp by 25% or more as needed to reduce rapid responses. • For patients who do not respond adequately, if the hemoglobin has not increased by more than 1 g/dL after 4 weeks of therapy, increase the dose by 25%. • For patients who do not respond adequately over a 12-week escalation period, increasing the Aranesp dose further is unlikely to improve response and may increase risks. Use the lowest dose that will maintain a hemoglobin level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue Aranesp if responsiveness does not improve

References:

I. Aranesp [package insert]. Thousand Oaks, CA, Amgen Inc.; July 2015
II. Centers for Disease Control and Prevention. National Chronic Kidney Disease Fact Sheet: General Information and National Estimates on Chronic Kidney Disease in the United States, 2010. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2010.
III. FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis- Stimulating Agents (ESAs) in chronic kidney disease. (6-24-2011)
IV. FDA News; BDA Strengthens Safety Information for Erythropoiesis-Stimulating Agents (ESAs). P07-40, 03/09/07.
V. Wauters, Isabelle; Vansteenkiste, Johan Erythropoiesis-stimulating agents in cancer patients: reflections on safety. Expert Review of Clinical Pharmacology. 4(4):467-476, July 2011.

VI. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target

Bydureon (exenatide)

Covered uses	All FDA approved indications
Exclusion Criteria	Bydureon is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
Required Medical Information	1. Medical diagnosis of type 2 diabetes mellitus. 2. Previous trial (or demonstrated contraindication/intolerance) of a metformin-containing product **AND** at least 2 of the following agents: sulfonylurea, thiazolidinedione, or DPP-4 inhibitor. 3. Requested dose is 2 mg administered every 7 days.
Age restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A

References:

1) Bydureon [package insert]. AstraZeneca Pharmaceuticals. Wilmington, DE. September 2015

Zetia (ezetimibe)

Covered uses	All medically accepted indications
Exclusion Criteria	Pregnancy
Required Medical Information	1. Stated diagnosis of primary hyperlipidemia alone or in combination with a HMG-CoA Reductase Inhibitor (statin) **AND** 2. Trial of atorvastatin calcium 80mg **OR** 3. Stated diagnosis of mixed hyperlipidemia in combination with fenofibrate **OR** **4.** Stated diagnosis of homozygous familial hypercholesterolemia (HoFH), in combination with atorvastatin or simvastatin **OR** 5. Stated diagnosis of homozygous sitosterolemia (phytosterolemia) **OR** 6. Contraindication or intolerance to HMG-CoA Reductase Inhibitors (Statin) therapy
Age restrictions	Age 10 or greater
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

1. Lipitor [package insert]. New York, NY: Pfizer Inc.; 2012.
2. Third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). National Heart, Lung, and Blood Institute. National Institutes of Health (NIH). 2004
3. Zetia [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2012.
4. Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Lloyd-Jones DM, Blum CB, McBride P, 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. J Am Coll Cardiol. 2013 Nov 7.

Glatiramer acetate subcutaneous solution

Covered uses	All medically accepted indications
Exclusion Criteria	
Required Medical Information	Preferred agent: Glatiramer acetate 20 mg Stated diagnosis from neurologist of one of the following: 1. Relapsing-remitting MS 2. Secondary progressive MS with relapses 3. Progressive-relapsing MS Statement may include: 1. A first MS attack with document MRI scan abnormalities characteristic of MS, **OR** 2. Evaluation documenting EITHER: a. History of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, **OR** b. History of one focal neurological deficit which has resolved, and an MRI suggestive of MS.
Age restrictions	Age 18 years or greater
Prescriber Restrictions	Neurologist
Coverage Duration	1 year
Other Criteria	

Reference

1. Glatopa [package insert]. Sandoz, Inc. Princeton, NJ. June 2015

Rebif (interferon beta-1a)

FDA approved Indications	All medically accepted indications
Exclusion Criteria	
Required Medical Information	Stated diagnosis from neurologist of : 1. definite relapsing-remitting MS, 2. secondary progressive MS with relapses, 3. or progressive relapsing MS Statement may include: 1. a first MS attack with documented MRI scan abnormalities characteristic of MS, **OR** 2. evaluation documenting EITHER: a. history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, **OR** b. history of one focal neurological deficit which has resolved, and an MRI suggestive of MS
Age restrictions	18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	1 year
Other Criteria	

References:

1. Product Information: Rebif(R) subcutaneous injection, interferon beta 1a subcutaneous injection. EMD Serono, Inc. and Pfizer Inc. (per FDA), Rockland, MA, 2012.

Extavia (interferon beta-1b)

Covered uses	1. All medically accepted indications
Exclusion Criteria	
Required Medical Information	Stated diagnosis from neurologist of : 1. definite relapsing-remitting MS, 2. secondary progressive MS with relapses, 3. or progressive relapsing MS Statement may include: 1. a first MS attack with documented MRI scan abnormalities characteristic of MS, **OR** 2. evaluation documenting EITHER: a. history of at least two focal neurological deficits (e.g. loss of vision, double vision, localized numbness or weakness), in which the first resolved and the second followed after a period of at least 6 months, **OR** b. history of one focal neurological deficit which has resolved, and an MRI suggestive of MS.
Age restrictions	Age 18 years or greater
Prescriber Restrictions	Neurologist
Coverage Duration	1 year
Other Criteria	

Reference
Extavia [package insert] Novartis Pharmaceuticals, Inc. East Hanover, NJ, March 2012.

Corlanor (ivabradine)

Covered uses	All FDA Approved Indications
Exclusion Criteria	• Acute decompensated heart failure • Severe hepatic impairment (Child-Pugh C) • Pregnancy • Concomitant use of strong cytochrome CYP3A4 inhibitors
Required Medical Information	Approve based on diagnosis of stable, symptomatic chronic heart failure with the following: • Left ventricular ejection fraction of 35% or less • Sinus rhythm with resting heart rate of 70 or greater BPM (before treatment initiation) o Dosage may be adjusted to achieve resting heart rate of 50-60 BPM after treatment has been initiated • Currently on maximally tolerated doses beta-blockers or contraindication to beta-blockers
Age restrictions	Age 18 years or greater
Prescriber Restrictions	Cardiologist
Coverage Duration	1 year
Other Criteria	Recommended dosing: 5 mg twice daily Maximum dosing: 7.5 mg twice daily

References:

1. Corlanor (Ivabradine) package insert. Thousand Oaks, CA: Amgen Inc.; 2015 Apr.

Nucala (mepolizumab)

Covered uses	All FDA Approved Indications
Exclusion Criteria	• Use as treatment for acute asthma symptoms or acute exacerbations
Required Medical Information	Documentation of all of the following: • Diagnosis of severe asthma with an eosinophilic phenotype o Blood eosinophil count greater than or equal to 300 cells/mcL within the previous 12 months **OR** o Blood eosinophils count greater than or equal to 150 cells/mcL at initiation of therapy • Submitted notes or claims data indicate that Nucala will be used as add-on maintenance treatment with an inhaled corticosteroid, long-acting beta2 agonist, leukotriene receptor antagonist, and/or theophylline • Dosage is 100 mg once every 4 weeks • Member has been enrolled in WellCare's Asthma disease management program for 6 months (or less depending on clinical situation) Reauthorization Treatment with Nucala has resulted in clinical improvement as documented by one or more of the following: • Decreased utilization of rescue medications **OR** • Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids) **OR** • Increase in predicted FEV1 from pretreatment baseline **OR** • Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.
Age restrictions	12 years and older
Prescriber Restrictions	Allergist, Pulmonologist, or Immunologist
Coverage Duration	1 year
Other Criteria	N/A

References:

1) Nucala [package insert]. Research Triangle Park, NC, GlaxoSmithKline

Xolair (omalizumab)

Covered uses	All FDA approved indications
Exclusion Criteria	N/A
Required Medical Information	Documentation of the following: 1) Moderate to severe persistent asthma in adults and adolescents 12 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). a) IgE levels prior to initiation of therapy **AND** i. IgE level of 30 IU/ml to 700 IU/ml only b) RAST or Allergy skin test - Positive skin test or in vitro reactivity to a perennial aeroallergen **AND** c) Weight between 30 - 150kg (current weight must be provided) **AND** d) Peak flow rate less than 80% of predicted with at least a 30% variability **AND** e) Member has been enrolled in WellCare's Asthma disease management program for 6 months (or less depending on clinical situation) 2) Moderate to severe persistent asthma in children 6 to <12 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). a. Xolair will be used as add-on therapy **AND** b. Member has been enrolled in WellCare's Asthma disease management program for 6 months (or less depending on clinical situation) 3) Chronic Idiopathic Urticaria (CIU), refractory to all preferred agents: H1 antihistamines, corticosteroids and leukotriene modifiers, each used for a minimum of 30 days within the last 3 months AND for which allergic urticaria and other non-idiopathic urticaria is ruled out. Reauthorization For asthma, treatment with Xolair has resulted in clinical improvement as documented by one or more of the following: • Decreased utilization of rescue medications **OR** • Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with

	systemic corticosteroids) **OR** • Increase in predicted FEV1 from pretreatment baseline **OR** Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing. For Chronic Idiopathic Urticaria (CIU), treatment with Xolair has resulted in reduced itch or hive count.
Age restrictions	Age 6 years or greater
Prescriber Restrictions	Pulmonologist, Allergist, or Immunologist
Coverage Duration	1 year
Other Criteria	N/A

References:

1. Product Information: XOLAIR(R) subcutaneous injection, omalizumab subcutaneous injection. Genentech, Inc, South San Francisco, CA, 2010.
2. Product Information: XOLAIR(R) subcutaneous injection powder, omalizumab subcutaneous injection powder. Genentech, Inc. (per manufacturer), South San Francisco, CA, July 2016

Oxandrin (oxandrolone)

Covered uses	All medically accepted indications
Exclusion Criteria	Pregnancy X
Required Medical Information	Diagnosis of: • Bone pain: For the relief of the bone pain frequently accompanying osteoporosis Preferred Alternative(s): Alendronate calcitonin Evista Fortical NSAIDS (meloxicam, naproxen, ibuprofen, ketoprofen) • Weight gain (Cachexia): Adjunctive therapy to promote weight gain in patients with AIDS associated wasting syndrome and after weight loss following extensive surgery, chronic infections or severe trauma Preferred Alternative: Megestrol • To offset the protein catabolism associated with prolonged administration of corticosteroids Preferred Alternative: Megestrol • Hereditary angioedema, for chronic prophylaxis Preferred Alternative: Danazol
Age restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Criteria for approval: Documentation of trial and failure of an adequate trial (1 month minimum) of at least one (1) preferred alternative.

References:

1. Product Information: OXANDRIN(R) tablets, oxandrolone tablets. Savient Pharmaceuticals, Inc., East Brunswick, NJ, 2005.

2. Caballero T , Baeza ML , Cabanas R , et al: Consensus statement on the diagnosis, management, and treatment of angioedema mediated by bradykinin. Part II. Treatment, follow-up, and special situations. J Investig Allergol Clin Immunol 2011; 21(6):422-441.

Biltricide (praziquantel)

Covered uses	All medically accepted indications
Exclusion Criteria	< 4 years of age
Required Medical Information	Medical documentation indicating use for treatment for: FDA LABELED INDICATIONS • Clonorchiasis caused by Clonorchis sinensis • Infection by Opisthorchis viverrini, or • Schistosomiasis cause by Schistosoma hematobium, Schistosoma japonicum, Schistosoma mansoni, Schistosoma mekongi • NON-FDA LABELED INDICATIONS • Cysticercosis (Preffered agent: Albenza) • Infection by Taeni (Preffered agent: Albenza) • Hymenolepiasis • Infection by Fasciolopsis buski • Infection by Heterophyes heterophyes, Intestinal fluke • Infection by Metagonimus yokogawai • Infection by Metorchis conjunctus, North American liver fluke • Infection by Paragonimus
Age restrictions	≥ 4 years of age
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Dosing • Clonorchiasis: 25 mg/kg ORALLY 3 times over 1 day (at 4 to 6 hr intervals) • Infection by Opisthorchis viverrini: 25 mg/kg ORALLY 3 times over 1 day (at 4 to 6 hr intervals) • Schistosomiasis: 20 mg/kg ORALLY 3 times over 1 day (at 4 to 6 hr intervals)

References:

I. Biltricide [package insert]. Wayne, NJ: Bayer Healthcare Pharmaceuticals, Inc.; 2011.

Daraprim (pyrimethamine)

Covered uses	FDA Approved Indications: For the treatment of toxoplasmosis, acute malaria, and chemoprophylaxis of malaria due to susceptible strains of plasmodia.
Exclusion Criteria	Megaloblastic anemia due to folate deficiency Hypersensitivity to pyrimethamine
Required Medical Information	Criteria for approval: 1) Toxoplasmosis a. Documented diagnosis AND b. Denotation that agent will be used in conjunction with a sulfonamide (i.e. sulfadiazine, sulfamethoxazole) * Preferred regimens for prophylaxis/treatment of Toxoplasmosis gondii encephalitis in HIV-infected include sulfamethoxazole/trimethoprim or atovaquone monotherapy or atovaquone plus sulfadiazine. 2) Acute malaria: a. Documented diagnosis AND b. Denotation that agent will be used in conjunction with a sulfonamide (i.e. sulfadiazine, sulfamethoxazole) AND c. Previous T/F treatment with a preferred FDA indicated medication (i.e. chloroquine, hydroxychloroquine, mefloquine, etc.) 3) Chemoprophylaxis of malaria a. Documented diagnosis AND b. Submission of specific strain(s) in the endemic area member is traveling to. Daraprim must be appropriate treatment according to CDC prevalence/resistance statistics. Note: Daraprim is not effective against P. vivax. *** For a complete list of malaria information by country, please visit the CDC website.* c. Previous T/F treatment of all preferred regimens (chloroquine, hydroxychloroquine, atovaquone/proguanil, mefloquine, and quinine) OR Must provide adequate rationale why preferred agents are unacceptable.
	Infants aged 2 months and above.
Prescriber Restrictions	None
Coverage Duration	1) Toxoplasmosis treatment: a. Adults: 8 Weeks b. Pediatrics: 4 Weeks

Applies to:
Florida Healthy Kids (EHK/WHK)
Georgia Medicaid (GMD)
`Ohana Health Plan (ZAB/ZMD)
Harmony Health Plan (IMD)
Kentucky Medicaid (KAB/KHK/KMD)
New Jersey Medicaid (JMD)
New York Medicaid (NMD)
South Carolina Medicaid (SMD)

	2) Acute Malaria treatment: 12 Weeks 3) Chemoprophylaxis treatment: Based on request
Other Criteria	In general, dosing for the elderly should be conservative. It is recommended to start at the lower end of the dosing range, taking into consideration the hepatic, renal, or cardiac functionality of the patient, and of concomitant disease or other drug regimens. Dosing: Toxoplasmosis *Adult*: 50 – 75 mg daily (with 1 – 4 g of a sulfonamide daily). This dosage is continued for 1 – 3 weeks, contingent on patient response and tolerability. The two drugs can then be reduced to one half of the initial dose for an additional 4 -5 weeks. *Pediatric:* 1mg/kg/day divided into 2 equal daily doses; after 2-4 days, the dose may be reduced to one half for approximately one month. (The typical sulfonamide dosage should be used in conjunction with Daraprim). Malaria prophylaxis *Adults, adolescents > 10 years of age*: 25 mg po once weekly *Pediatric (4-10 years of age):* 12.5 mg po weekly Malaria treatment 25 mg daily for 2 days; following clinical cure, administer a once-weekly chemoprophylaxis regimen for ≥10 weeks

References:

1) Daraprim [package insert]. Amedra Pharmaceuticals. Horsham, PA. Oct. 2014

Cinqair (reslizumab)

Covered uses	All FDA Approved Indications
Exclusion Criteria	• Use as treatment for acute asthma symptoms or acute exacerbations
Required Medical Information	Documentation of all of the following: • Diagnosis of severe asthma with an eosinophilic phenotype o Blood eosinophil count greater than or equal to 400 cells/mcL within the previous 4 weeks • Submitted notes or claims data indicate that Cinqair will be used as add-on maintenance treatment with an inhaled corticosteroid, long-acting beta2 agonist, leukotriene receptor antagonist, and/or theophylline • Dosage is 3 mg/kg once every 4 weeks • Member has been enrolled in WellCare's Asthma disease management program for 6 months (or less depending on clinical situation) Reauthorization Treatment with Cinqair has resulted in clinical improvement as documented by one or more of the following: • Decreased utilization of rescue medications OR • Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids) OR • Increase in predicted FEV1 from pretreatment baseline OR • Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.
Age restrictions	18 years and older
Prescriber Restrictions	Allergist, Pulmonologist, or Immunologist
Coverage Duration	1 year
Other Criteria	N/A

References:

1) Cinqair [package insert]. Frazer, PA, Teva Respiratory, LLC

Risperdal Consta (risperidone, extended release)

Covered uses	All medically accepted indications
Exclusion Criteria	Risperdal Consta should be avoided in populations with dementia-related psychosis. (Black Box warning)
Required Medical Information	1. Medical diagnosis of schizophrenia or bipolar 1 disorder 2. Must have failed at least 2 weeks of 2 oral atypical antipsychotics (aripiprazole, risperidone, paliperidone, ziprasidone, quetiapine, olanzapine, etc.) **OR** provide documentation of non-compliance, inability to swallow oral medications, or contraindication to oral atypical antipsychotics. 3. Requested dose is administered every 2 weeks.
Age restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Members currently taking this medication at the time of enrollment will not be required to meet prerequisites for authorization

References:

1) Risperdal Consta [package insert]. Janssen Pharmaceuticals, Inc. Horsham, PA. September 2016

Entresto (sacubitril/valsartan)

Covered uses	All FDA approved indications
Exclusion Criteria	NYHA Class I Pregnancy (Boxed Warning) History of Angioedema relative to previous ACE/ARB therapy Severe hepatic impairment (Child-Pugh C) Concomitant use of aliskiren in diabetics Concomitant use of an ACE inhibitor – washout period required.
Required Medical Information	Criteria for approval: 1. Documentation of chronic heart failure status: NYHA Class II – IV **- AND-** 2. Documentation of reduced ejection fraction of ≤ 40% **- AND-** 3. Must provide information indicating: a. The patient does not have a history of angioedema. b. The patient does not have severe hepatic impairment. c. If diabetic: confirm patient is not taking an aliskiren based medication. d. If child-bearing age: confirm negative pregnancy test.- e. Confirm patient will be taking in conjunction with a beta blocker indicated for heart failure. Criteria for reauthorization: Documentation of improvement in ejection fraction, symptoms, decrease in hospitalization, etc.
Age restrictions	Age 18 years or greater
Prescriber Restrictions	Cardiologist Cardiac care specialist
Coverage Duration	12 months
Other Criteria	Must be administered as a replacement for an ACE inhibitor or ARB and used in combination with other heart failure therapies. 1. Recommended Dosing: **Initial Therapy**: The recommended starting dose is 49/51 mg twice-daily. **Maintenance Dose:** Double the dose after 2 to 4 weeks to the target dose of 97/103 mg twice daily, if tolerable.

2. Dosing Adjustments:

Criterion	Dose
Previously taking low doses of ACE inhibitor/ARB OR has never taken these agents. (See table below to evaluate)**	24/26 mg twice-daily
Has history of severe renal impairment (eGFR<30ml)	24/26 mg twice-daily
Moderate hepatic impairment	24/26 mg twice-daily

* For maintenance, can double the dose every 2 to 4 weeks to the target dose of 97/103 mg twice daily.

References:

1.) Entresto [package insert]. Novartis, East Hanover, NJ. July 2015.
2.) ACCF/AHA Practice Guideline: 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Clyde W. Yancy, et al. *Circulation*. 2013;128:e240-e327, published online before print June 5 2013, doi:10.1161/CIR.0b013e31829e8776.
3.) Yancy CW, Jessup M, Bozkurt B, et al. 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Am Coll Cardiol.* 2016;():. doi:10.1016/j.jacc.2016.05.011.

Sildenafil

Covered uses	All FDA approved indications
Exclusion Criteria	Sildenafil is not covered for the diagnosis of: • Erectile dysfunction/impotence • Pulmonary Hypertension o World Health Organization group 2 - 5
Required Medical Information	Documented diagnosis of: Pulmonary arterial hypertension (Idiopathic, inherited, due to drugs/toxins, connective tissue diseases, etc.) • World Health Organization group 1 with NYHA class II or III symptoms
Age restrictions	N/A
Prescriber Restrictions	Pulmonologist or Cardiologist
Coverage Duration	1 year
Other Criteria	Cover only 20mg tabs three times a day. Sildenafil should not be used in combination with organic nitrates.

References:

1. Product Information: REVATIO(R) oral tablets, oral suspension, intravenous injection, sildenafil oral tablets, oral suspension, intravenous injection. Pfizer Labs (per FDA), New York, NY, 2014.

Applies to:
Nebraska Family Planning (CHP599)

sodium hyaluronate/hyaluronic acid/hylan G-F 20 Supartz, Synvisc, Synvisc One, Euflexxa, Hyalgan, Orthovisc, Gel-One, Monovisc

Covered uses	All FDA-approved indications
Exclusion Criteria	Viscosupplementation is considered experimental and investigational for any indication other than osteoarthritis of the knee. These include, but are not limited to: • Chondromalacia patellae • Facet joint arthropathy • Osteochondritis dissecans • Patellofemoral arthritis • Patellofemoral syndrome • Plantar nerve entrapment syndrome • For use in joints other than the knee • Active synovitis When a repeat series of injections is initiated prior to six months after completion of the previous course of treatment.
Required Medical Information	Preferred Agent: SUPARTZ Treatment of pain in osteoarthritis (OA) of the knee Failure to respond adequately to **two** of the following for at least 3 consecutive months: 1. conservative nonpharmacologic therapy (low-impact aerobic exercises, neuromuscular education, weight loss programs, formal physical therapy) **OR** 2. simple analgesics (e.g., topical or oral NSAIDs, Tramadol) **OR** 3. intra-articular corticosteroid injection therapy
Age restrictions	Gel-One, Synvisc, Synvisc-One: 21 years or older All others: 18 years or greater
Prescriber Restrictions	Orthopedic specialist Interventional pain physician Rheumatologist
Coverage Duration	Monovisc/Synvisc-One/Gel-One: 7 months All others: 6 weeks

Applies to:
Nebraska Family Planning (CHP599)

Other Criteria	Quantity Limit: Orthovisc: 1 injection weekly for 3-4 weeks Euflexxa: 1 injection weekly for 3 weeks Supartz: 1 injection weekly for 5 weeks Hyalgan: 1 injection weekly for 5 weeks Synvisc: 1 injection weekly for 3 weeks Synvisc-One: 1 injection per treatment course Gel-One: 1 injection per treatment course Monovisc: 1 injection per treatment course

References:

1. Product Information: Supartz(R), sodium hyaluronate injection. Smith & Nephew Inc., Memphis, TN, 2004.
2. Product Information: HYALGAN(R) injection, sodium hyaluronate injection. Sanofi-Synthelabo,Inc, New York, NY, 2001.
3. Product Information: Orthovisc(R), high molecular weight hyaluronan. Ortho Biotech, Raritan, NJ, 2004.
4. Product Information: Hyalgan®, sodium hyaluronate. Sanofi-Synthelabo, New York, New York, 2000.
5. Product Information: Synvisc(R), Hylan G-F 20. Genzyme Corporation, Ridgefield, New Jersey, USA, 2004.
6. Viscosupplementation treatment of arthritis. American Academy of Orthopaedic surgeons. Website: http://orthoinfo.aaos.org/topic.cfm?topic=a00217. Published March 2014. Accesse May 2015.

Applies to:
Nebraska Family Planning (CHP599)

ADCIRCA (tadalafil)

Covered uses	All FDA Approved Indications
Exclusion Criteria	Tadalafil is not covered for the diagnosis of: • Erectile dysfunction/impotence • Pulmonary Hypertension o World Health Organization group 2 - 5
Required Medical Information	Documented diagnosis of: Pulmonary arterial hypertension (Idiopathic, inherited, due to drugs/toxins, connective tissue diseases, etc.) • World Health Organization group 1 with NYHA class II or III symptoms: PAH combination therapy: Tadalafil is commonly used with ambrisentan PAH monotherapy: sildenafil is preferred PDE-5 inhibitor
Age restrictions	Age 18 years or greater
Prescriber Restrictions	Cardiologist or Pulmonologist
Coverage Duration	1 year
Other Criteria	Tadalafil should not be used in combination with organic nitrates.

References:

1. Adcirca (tadalafil) [product monograph]. Toronto, Ontario, Canada: Eli Lilly Canada Inc; January 2015
2. N. Galie, J.A. Barbera, A.E. Frost, *et al.*Initial Use of Ambrisentan plus Tadalafil in Pulmonary Arterial Hypertension. N. Engl. J. Med., 373 (2015), pp. 834–844

Applies to:
Nebraska Family Planning (CHP599)

Aubagio (teriflunomide)

Covered uses	All FDA-approved indications
Exclusion Criteria	• Pregnancy • Planning pregnancy • Severe hepatic impairment • Concomitant leflunomide therapy • Positive TB test • AST/ALT >2 x ULN, Bilirubin levels > 1.2 mg/dl • Lymphocyte count < 0.91×10^{9} /L
Required Medical Information	• Statement of FDA approved indication: Relapsing forms of multiple sclerosis (MS) • Baseline serum AST/ALT, bilirubin and CBC levels (obtained within 30 days of initiation) • Screen for TB
Age restrictions	Age 18 years or greater
Prescriber Restrictions	Neurologist
Coverage Duration	1 year
Other Criteria	

References

1. Aubagio [package insert]. Genzyme Corporation, Cambridge, MA 02142. A Sanofi Company. 2012

Applies to:
Nebraska Family Planning (CHP599)

Bethkis (tobramycin nebulized)

Covered uses	All FDA approved indications
Exclusion Criteria	Efficacy and safety have not been demonstrated in patients with forced expiratory volume in 1 second (FEV_1) less than 40% or greater than 80% predicted, or in patients colonized with *Burkholderia cepacia.*
Required Medical Information	Diagnosis of Cystic fibrosis AND LABS: Recent Culture and Sensitivity report with documented diagnosis of *Pseudomonas aeruginosa* (i.e., positive sputum culture for *Pseudomonas aeruginosa*).
Age restrictions	Age 6 years or greater
Prescriber Restrictions	Pulmonologist, Infectious Disease Specialist
Coverage Duration	1 year
Other Criteria	The recommended dosage for patients six years of age and older is to administer one single-use ampule (300 mg/4 mL) twice daily by oral inhalation in repeated cycles of 28 days on drug, followed by 28 days off drug.

References:

1. Bethkis [package insert]. Woodstock, IL: Cornerstone Therapeutics Inc.; December 2014.

Applies to:
Nebraska Family Planning (CHP599)

Trelstar (triptorelin)

Covered uses	All medically accepted indications
Exclusion Criteria	Pregnancy
Required Medical Information	Statement of medically accepted indication: 1. Advanced prostate cancer 2. Premenopausal women with hormone sensitive advanced breast cancer 3. Endometriosis with associated dysmenorrhea or uterine leiomyomata • Trial and Failure of: Preferred contraceptives
Age restrictions	
Prescriber Restrictions	Oncologist
Coverage Duration	1 year
Other Criteria	Members currently taking this medication at time of enrollment will not be required to meet prerequisites for prior authorization.

References:
1. Product Information: TRELSTAR(R) DEPOT for injectable suspension, triptorelin pamoate for injectable suspension. Watson Pharma,Inc., Corona, CA, 2005.
2. Product Information: TRELSTAR(R) LA IM injection, triptorelin pamoate IM injection. Watson Pharma,Inc, Corona, CA, 2006.