denotes change in current criteria
denotes new criteria

Myfembree

Myfembree *is a combination of relugolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.*

CRITERIA FOR APPROVAL:

1. Patient must be a premenopausal woman diagnosed with heavy menstrual bleeding associated with uterine leiomyomas (fibroids); **AND**

2. Patient must be within the age range as recommended by the FDA label; **AND**

3. Patient must not be pregnant; **AND**

4. Patient must not be diagnosed with osteoporosis; **AND**

5. Patient has failed a 90-day trial with one agent from **ONE** the following categories (unless contraindicated):

    a. Combination Estrogen/Progestin contraceptives
    b. Progestin therapy (oral, transdermal, vaginal ring, IUD, or injections)
    c. Tranexamic acid

Initial prior authorization will be for 90 days. Continuation of coverage requires documentation of clinically significant improvement in symptoms as compared to that seen using previous therapy.

Maximum length of therapy is limited to 24 months due to the risk of continued bone loss, which may not be reversible.

MABS, ANTI- IL/IgE

Current Criteria:

CLASS PA CRITERIA
For FDA-approved indications, non-preferred agents require a ninety (90) day trial of Xolair. **Full PA Criteria may be found on the PA Criteria page by clicking the hyperlink.**

Proposed Criteria:

Non-preferred agents require ninety (90) day trials of all preferred agents which are indicated for the diagnosis. **Full PA Criteria may be found on the PA Criteria page by clicking the hyperlink.**

MABS, ANTI-IL/IgE		
CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of all preferred agents which are indicated for the diagnosis. **Full PA Criteria may be found on the PA Criteria page by clicking the hyperlink.**		
DUPIXENT (dupilumab) FASENRA (benralizumab XOLAIR (omalizumab)	NUCALA SYRINGE/VIAL (mepolizumab) NUCALA AUTO INJECTOR (mepolizumab)	

Dupixent:

DUPIXENT *is an interleukin-4 receptor alpha antagonist indicated:*

I. For the treatment of patients aged 6 years and older 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.

II. As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

III. As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

I. For the Indication of Atopic Dermatitis, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with an allergist, immunologist or dermatologist; **AND**

2. Documented diagnosis of moderate to severe Atopic Dermatitis (AD). Documentation must include the affected BSA, areas of involvement and severity of symptoms; **AND**

3. The patient must be within the age range as recommended by the FDA label and indication; **AND**

4. Affected body surface area is greater than or equal to 10%; **AND**

5. Patient has failed to find relief of symptoms after a minimum of 30-day trials of ~~all~~ two agents from the following list in the last 12 months:

    a. Medium to High potency topical corticosteroid*
    b. Elidel
    c. Eucrisa
    d. Tacrolimus

~~*Requirement for topical corticosteroid therapy will be excluded for patients with sensitive areas of involvement such as the face, skin folds or genitals.~~

*Trial of medium to high potency topical steroid is required unless the affected area involves sensitive areas such as the face, skin folds or genitals. However, a trial of two other agents among the list above, are still required prior to Dupixent approval.

Initial approval of Dupixent for atopic dermatitis will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response (including current affected BSA and severity of symptoms).

II. For the indication of Asthma, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with an allergist, immunologist or pulmonologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. Patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days; **AND EITHER**

4. Documentation must be supplied indicating one of the following:
    a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3%; **OR**
    b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 150 cells/mcL within the past 6 weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; **OR**
    c. Claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Dupixent for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

III. For the indication of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), prior authorization requests may be approved if the following criteria are met:

1. Must be prescribed by or in consultation with, an ENT, allergist, or other suitable specialist; **AND**

2. Member must have a diagnosis of CRSwNP which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid~~. If the member has not trialed Xhance intranasal steroid, then they must also fail 3-months of therapy with that product~~; **AND**

3. The patient must be within the approved age range according to the FDA label and indication; **AND**

4. Dupixent is only approvable as add-on therapy for CRSwNP.

Initial approval of Dupixent for CRSwNP will be for 90 days. Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Dupixent was supplementing).

Fasenra:

FASENRA is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Prior authorization requests for Fasenra may be approved if the following criteria are met:

TREATMENT OF EOSINOPHILIC ASTHMA:

1. Must be prescribed by or in consultation with an allergist, immunologist or pulmonologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. Patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days; **AND**

4. Documentation must be supplied indicating **one** of the following:

a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3%; **OR**
b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 150 cells/mcL within the past 6 weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; **OR**
c. Claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Fasenra for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

Xolair:

***Xolair vials are preferred for all indications over prefilled syringes. Prefilled syringes may be approved if determined appropriate by the medical provider AND the member or caregiver will be the individual administering Xolair.* Candidates for self-administration must have previously received at least 3 doses of Xolair.**

Xolair is an anti-IgE antibody indicated for:

- *Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.*
- *Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.*
- *Add-on maintenance treatment of nasal polyps in adults with inadequate response to nasal corticosteroids*

Prior authorization requests for Xolair may be approved if the following criteria are met:

For moderate to severe persistent asthma
1) Patient is six (6) years of age or older; **AND**
2) Must be prescribed by a board-certified pulmonologist or board-certified allergist; **AND**
3) Current body weight is between 20kg and 150kg; **AND**
4) If the patient currently smokes they must be enrolled in a smoking cessation program; **AND**
5) Patient is symptomatic despite receiving recommended first line treatments (including high dose inhaled corticosteroids + LABA) and exhibiting compliance with those treatments; **AND**
6) Patient has reacted positively to a perennial aeroallergen skin or blood test; **AND**
7) Patient must have an IgE level not less than 30 IU/ml or more than the Manufacturer's recommendation, based on weight. (The patient's weight and pretreatment serum IgE must be presented to review dosing).

For moderate to severe Chronic Idiopathic Urticaria:
1) Current diagnosis must be Chronic Idiopathic Urticaria, (documentation supporting diagnosis must be provided with PA request); **AND**
2) Patient must be twelve (12) years of age or older; **AND**

3) Prescribed written by a board-certified Allergist, Immunologist, or Dermatologist; **AND**
4) Patient must have documented failure of 60-days of therapy with a 2nd-generation H1 antihistamine prescribed at 2x – 4x the usual dose; **AND**
5) At least 30 days of therapy using a combination of a 2nd-generation H1 antihistamine (prescribed at 2x – 4x the usual dose) concurrent with one or more of the following treatment options:
    a. Add a different 2nd-generation H1 antihistamine
    b. Add an H2 antihistamine
    c. Add a 1st generation antihistamine at night
    d. Add montelukast (or other leukotriene receptor antagonist).
    e. Add high-potency antihistamine hydroxyzine or doxepin and titrate as tolerated
6) Patients who do not tolerate at least 2x the normal listed dose of the 2nd generation H1 antihistamines (see below) will be required to try each agent (and possibly combinations of these agents) until they either tolerate one of them to the required dosing range or they have documented intolerance to all of them.

TREATMENT OF NASAL POLYPS:

1) Must be prescribed by or in consultation with, an ENT, allergist, or other suitable specialist; **AND**

2) The patient must have a diagnosis of nasal polyps which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid; **AND**

3) The patient must be within the approved age range according to the FDA label and indication; **AND**

4) Xolair is only approvable as add-on therapy for nasal polyps.

Initial approval of Xolair for nasal polyps will be for 90 days. Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Xolair was supplementing).

Nucala:

NUCALA is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Treatment of adult and pediatric patients ≥12 years of age with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable nonhematologic secondary cause.
- : Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with an inadequate response to nasal corticosteroids.

Prior authorization requests for Nucala may be approved if the following criteria are met:

TREATMENT OF EOSINOPHILIC ASTHMA:

1. Must be prescribed by or in consultation with an allergist, immunologist or pulmonologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. Patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days; **AND**

4. Documentation must be supplied indicating **one** of the following:
    a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3%; **OR**
    b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 150 cells/mcL within the past 6 weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; **OR**
    c. Claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Nucala for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

TREATMENT OF EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA):

1. Patient must have a documented diagnosis of EPGA (also known as Churg-Strauss Syndrome) with the patient meeting at least 4 of the following diagnostic criteria:
    a. Asthma
    b. Eosinophilia of > 10% in peripheral blood
    c. Paranasal sinusitis
    d. Pulmonary infiltrates, sometimes transient
    e. Histologic evidence of vasculitis with extravascular eosinophils
    f. Multiple mononeuropathy or polyneuropathy

    AND

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. Patient has failed to achieve remission of symptoms following at least a 90-day course of systemic glucocorticoid therapy equivalent to (or greater than) 7.5 mg/day of oral prednisone PLUS immunosuppressive therapy such as, but not restricted to, cyclophosphamide, methotrexate or azathioprine (unless contraindicated) *

* If the provider feels that immunosuppressive therapy is contraindicated, they must document the reason for this.

Initial approval of Nucala for EGPA will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response.

TREATMENT OF HYPEREOSINOPHILIC ASTHMA:

1. Must be prescribed by or in consultation with an allergist, immunologist, hematologist or pulmonologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. The patient must have a blood eosinophil count of ≥ 1,000 cells per mcl; **AND**

4. The patient has had at least 2 HES flares within the past 12 months; **AND**

5. The patient is on a stable dose of background HES therapy (chronic or episodic corticosteroids, immunosuppressive, or cytotoxic therapy) for at least 4 weeks prior to treatment initiation.

Initial approval of Nucala for HES will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response.

TREATMENT OF CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP):

1. Must be prescribed by or in consultation with, an ENT, allergist, or other suitable specialist; **AND**

2. The patient must have a diagnosis of chronic rhinosinusitis with nasal polyps which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid; **AND**

3. The patient must be within the approved age range according to the FDA label and indication; **AND**

4. Nucala is only approvable as add-on therapy for CRSwNP.

Initial approval of Nucala for CRSwNP will be for 90 days. Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Nucala was supplementing).

Cytokine and CAM Antagonists

Current Criteria:

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of all preferred agents which are indicated for the diagnosis, unless one (1) of the exceptions on the PA form is present. *Patients stabilized for at least 6-months on their existing non-preferred regimen shall be grandfathered (provided the current therapy is for a labeled indication). All off-label requests require review by the Medical Director.* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

Side bar criteria:
*For all requests, the most cost-effective alternative will be approved. Should the provider request a different infliximab product, documentation of contraindication or allergy to the required agent must be provided. As of 10/1/2021, Avsola is the most cost-effective alternative.

Proposed Criteria:

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of all preferred agents which are indicated for the diagnosis, unless one (1) of the exceptions on the PA form is present. *Patients stabilized for at least 6-months on their existing non-preferred regimen shall be grandfathered (provided the current therapy is for a labeled indication AND a more cost-effective biosimilar product is not available). In cases where a biosimilar exists but is also non-preferred, the PA vendor shall advise the provider which product is the most cost-effective agent.* ***All off-label requests require review by the Medical Director.***

****Side bar criteria removed as Avsola is now preferred but incorporated into clinical PA criteria.***

Taltz

Current criteria-

*Taltz will be authorized for treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis only after inadequate response to a ninety (90) day trial of one preferred agent.

Proposed Criteria

*Taltz will be authorized for treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis only after inadequate response to a ninety (90) day- trial of one preferred ANTI-TNF agent.

CYTOKINE & CAM ANTAGONISTS[CL]

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of all preferred agents which are indicated for the diagnosis, unless one (1) of the exceptions on the PA form is present. *Patients stabilized for at least 6-months on their existing non-preferred regimen shall be grandfathered (provided the current therapy is for a labeled indication AND a more cost-effective biosimilar product is not available). In cases where a biosimilar exists but is also non-preferred, the PA vendor shall advise the provider which product is the most cost-effective agent.* ***All off-label requests require review by the Medical Director.***

ANTI-TNFs		
AVSOLA (infliximab) ENBREL (etanercept) HUMIRA (adalimumab) SIMPONI subcutaneous (golimumab)	CIMZIA (certolizumab pegol) INFLECTRA (infliximab) REMICADE (infliximab) RENFLEXIS (infliximab*) SIMPONI ARIA (golimumab)	

ACTEMRA subcutaneous (tocilizumab) KINERET (anakinra) OTEZLA (apremilast) ORENCIA CLICKJET/VIAL (abatacept) TALTZ (ixekizumab)* XELJANZ (tofacitinib)	ACTEMRA ACTPEN (tocilizumab) COSENTYX (secukinumab) ENTYVIO (vedolizumab) ILARIS (canakinumab) ILUMYA (tildrakizumab) KEVZARA (sarilumab) OLUMIANT (baricitinib) ORENCIA SYRINGE (abatacept) RINVOQ ER (upadacitinib) SILIQ (brodalumab) SKYRIZI (risankizumab) STELARA subcutaneous (ustekinumab) TREMFYA (guselkumab) XELJANZ XR (tofacitinib)	*Taltz will be authorized for treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis only after inadequate response to a ninety (90) day trial of one preferred ANTI-TNF agent.

HYPOGLYCEMIA TREATMENTS

Class PA Criteria: ***Non-preferred agents require clinical reasoning beyond convenience why the preferred glucagon products cannot be used.***

**Baqsimi spray and Zegalogue may only be approved after a trial of a preferred reconstituted glucagon agent.*

HYPOGLYCEMIA TREATMENTS		
CLASS PA CRITERIA: Non-preferred agents require clinical reasoning beyond convenience why the preferred glucagon products cannot be used.		
BAQSIMI SPRAY (glucagon)* GLUCAGEN VIAL (glucagon) glucagon emergency kit (labeler 00002) ZEGALOGUE (dasiglucagon)*	glucagon emergency kit GVOKE (glucagon)	*Baqsimi spray and Zegalogue may only be approved after a trial of a preferred reconstituted glucagon agent.

AEMCOLO- indicated for travelers' diarrhea

*****Aemcolo may be authorized after a trial of Xifaxan 200mg tablets.***

ANTIBIOTICS, GI & RELATED AGENTS		
CLASS PA CRITERIA: Non-preferred agents require a fourteen (14) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
FIRVANQ (vancomycin) metronidazole tablet neomycin tinidazole XIFAXAN 200 MG (rifaximin)*	AEMCOLO (rifamycin) tablet** DIFICID (fidaxomicin)* FLAGYL (metronidazole) metronidazole capsule paromomycin VANCOCIN (vancomycin) vancomycin XIFAXAN 550 MG (rifaximin)*	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. **Aemcolo may be authorized after a trial of Xifaxan 200mg tablets.

Epidiolex ***Auto PA***

Epidiolex may be authorized after a trial of two of the following agents within the past 12 months: clobazam, levetiracetam, valproate, lamotrigine, topiramate, rufinamide, or felbamate.

ANTICONVULSANTS

CLASS PA CRITERIA: For a diagnosis of seizure disorder, non-preferred agents require a fourteen (14) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present; patients currently on established therapies shall be grandfathered.

For all other diagnoses, non-preferred agents require a thirty (30) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

In situations where AB-rated generic equivalent products are available, "Brand Medically Necessary" must be hand-written by the prescriber on the prescription for the brand name product to be reimbursed.

CANNABINOIDS		
EPIDIOLEX SOLUTION (cannabidiol)[A]*		*Epidiolex may be authorized after a trial of two of the following agents within the past 12 months: clobazam, levetiracetam, valproate, lamotrigine, topiramate, rufinamide, or felbamate.

Rezurock

Rezurock may be authorized after a trial of two systemic treatments for chronic graft-versus-host disease. Examples of systemic therapy may include methylprednisolone, Imbruvica® (ibrutinib capsules and tablets), cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil and imatinib.

IMMUNOSUPPRESSIVES, ORAL		
CLASS PA CRITERIA: Non-preferred agents require a fourteen (14) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
azathioprine cyclosporine cyclosporine, modified mycophenolate mofetil sirolimus tacrolimus capsule	ASTAGRAF XL (tacrolimus) AZASAN (azathioprine) CELLCEPT (mycophenolate mofetil) ENVARSUS XR (tacrolimus) IMURAN (azathioprine) LUPKYNIS (voclosporin)* mycophenolic acid mycophenolic mofetil suspension MYFORTIC (mycophenolic acid) NEORAL (cyclosporine, modified) PROGRAF (tacrolimus) RAPAMUNE (sirolimus) REZUROCK (belumosudil)* SANDIMMUNE (cyclosporine) ZORTRESS (everolimus)	*Lupkynis requires a ninety (90) day trial of Benlysta prior to approval. Full PA criteria for Lupkynis may be found on the PA Criteria page by clicking the hyperlink. Rezurock may be authorized after a trial of two systemic treatments for chronic graft-versus-host disease. Examples of systemic therapy may include methylprednisolone, Imbruvica® (ibrutinib capsules and tablets), cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil and imatinib.

Ozobax (oral Baclofen solution)

*Ozobax may only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia.

MUSCULOSKELETAL RELAXANT AGENTS USED FOR SPASTICITY		
baclofen tizanidine tablets	DANTRIUM (dantrolene) dantrolene tizanidine capsules OZOBAX SOLUTION (baclofen)* ZANAFLEX (tizanidine)	Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present. *Ozobax may only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia.