denotes change in current criteria
denotes new criteria

Lyvispah/Fleqsuvy/oral baclofen solution

Oral baclofen solution, Fleqsuvy (baclofen suspension) and Lyvispah granules may only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia. In addition, Fleqsuvy and Lyvispah may only be authorized if there is a documented intolerance to oral baclofen solution.

MUSCULOSKELETAL RELAXANT AGENTS USED FOR SPASTICITY		
baclofen tizanidine tablets	baclofen solution* DANTRIUM (dantrolene) dantrolene FLEQSUVY (baclofen)* LYVISPAH GRANULE PACKET (baclofen)* tizanidine capsules 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. **Oral baclofen solution, Fleqsuvy (baclofen suspension) and Lyvispah granules may only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia. In addition, Fleqsuvy and Lyvispah may only be authorized if there is a documented intolerance to oral baclofen solution.*

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 in premenopausal women for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and* management of moderate to severe pain associated with endometriosis.

CRITERIA FOR APPROVAL:

1. Patient must be a premenopausal woman diagnosed with heavy menstrual bleeding associated with uterine leiomyomas (fibroids) or diagnosed with moderate to severe pain associated with endometriosis; **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. For heavy menstrual bleeding associate with uterine leiomyomas (fibroids): The 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

6. For moderate to severe pain associated with endometriosis:

   a. The patient has failed to achieve significant symptomatic relief with NSAID therapy (please provide documentation); **AND**

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

      1. Extended-cycle combined oral contraceptive OR progestin therapy
      2. GnRH agonist

Approval Duration: Initial approval will be for 90 days.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; **AND**

2. Patient has experienced 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.

denotes change in current criteria
denotes new criteria

Orilissa/Oriahnn

*Full PA criteria for Myfembree, Orilissa and Oriahnn may be found on the PA Criteria page by clicking the hyperlink. In addition, Orilissa and Oriahnn may only be approved if there is a documented side effect, allergy, or treatment failure with Myfembree. Use of GnRH receptor antagonists will be limited to 24 months.

PITUITARY SUPPRESSIVE AGENTS, LHRH[CL]		
CLASS PA CRITERIA: Unless otherwise noted, non-preferred agents are available only on appeal.		
FENSOLVI SYRINGE (leuprolide acetate) LUPANETA (leuprolide) LUPRON DEPOT KIT (leuprolide) LUPRON DEPOT-PED KIT (leuprolide) MYFEMBREE (relugolix, estradiol, norethindrone)*	leuprolide ORIAHNN (elagolix-estradiol-norethindrone)* ORILISSA (elagolix)* SUPPRELIN LA KIT (histrelin)	* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. *Full PA criteria for Myfembree, Orilissa and Oriahnn may be found on the PA Criteria page by clicking the hyperlink. In addition, Orilissa and Oriahnn may only be approved if there is

SYNAREL (nafarelin) TRELSTAR (triptorelin) TRIPTODUR (triptorelin) ZOLADEX (goserelin)		a documented side effect, allergy, or treatment failure with Myfembree. Use of GnRH receptor antagonists will be limited to 24 months.

denotes change in current criteria
denotes new criteria

Fintepla

Fintepla *is indicated for treatment of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome in patients 2 years of age and older*

CRITERIA FOR APPROVAL:

1. The patient has a diagnosis of Dravet Syndrome or Lennox-Gastaut syndrome; **AND**

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

3. Fintepla is prescribed by, or in consultation with a neurologist; **AND**

4. The prescriber, pharmacy, and patient must all be enrolled in the FINTEPLA REMS program; **AND**

5. Documentation of current baseline seizure activity per month must be provided; **AND**

6. For Dravet Syndrome: The patient must have treatment failure/inadequate response to valproate and clobazam. If there is an intolerance, allergy, or contraindication to valproate, one other preferred antiepileptic (such as topiramate or levetiracetam) must be trialed; **AND**

7. For Lennox-Gastaut syndrome: The patient must have treatment failure/inadequate response or intolerance to valproate, lamotrigine and Clobazam, unless contraindicated

8. Evaluation with echocardiography for valvular disease and pulmonary hypertension is required before treatment, every six months during treatment, and once three to six months after treatment. ~~to monitor for valvular heart disease and pulmonary hypertension.~~

9. Will not be approved if prescribed as monotherapy for LGS or Dravet.

Approval Duration:

Initial approval will be for 6 months.

Criteria for reauthorization:

denotes change in current criteria
denotes new criteria

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. Documented decrease from baseline in seizure frequency per month must be provided.

Continuation of therapy approvals will be granted for 12 months.

denotes change in current criteria
denotes new criteria

Dupixent

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

Atopic Dermatitis
for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe AD 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.

Asthma
as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitations of Use: Not for the relief of acute bronchospasm or status asthmaticus.

Chronic Rhinosinusitis with Nasal Polyposis
as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

Eosinophilic Esophagitis
for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

Prurigo Nodularis
for the treatment of adult patients with prurigo nodularis (PN).

For the indication of Eosinophilic Esophagitis, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or gastroenterologist; **AND**
2. The patient must be within the age range as recommended by the FDA label and indication; **AND**
3. The patient has an eosinophilic count ≥15 eosinophils per high-power microscopy field (eos/hpf); **AND**
4. The patient has symptoms of dysphagia or prior history of esophageal dilation; **AND**
5. The patient has had a 90-day trial resulting in an inadequate response to topical/systemic glucocorticoids, unless contraindicated.

Initial approval of Dupixent for Eosinophilic Esophagitis will be for 90 days. Additional therapy shall be approvable with documentation showing that the member has achieved a significant reduction in dysphagia symptoms since treatment initiation. ~~and has an esophageal intraepithelial eosinophil count of ≤6 eos/hp.~~

denotes change in current criteria
denotes new criteria

For the indication of Prurigo Nodularis, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with a dermatologist, allergist, or immunologist; **AND**
2. The patient must be within the age range as recommended by the FDA label and indication; **AND**
3. Patient has a Worst Itch Numeric Rating Scale (WI-NRS) score of ≥7 on a scale of 0 to 10; **AND**
4. The patient has at least 20 nodular lesions; **AND**
5. The patient has had a trial resulting in an inadequate response/treatment failure to a super potent topical corticosteroid or an intralesional corticosteroid, unless contraindicated.

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

denotes change in current criteria
denotes new criteria

Kesimpta

Kesimpta may be approved with documentation of treatment failure/inadequate treatment response after a 90-day trial of at least one preferred MS agent. Member must have a negative Hepatitis-B test, please provide documentation.

MULTIPLE SCLEROSIS AGENTS[CL]		
CLASS PA CRITERIA: All agents require a prior authorization and documented diagnosis of multiple sclerosis. Preferred oral agents require a ninety (90) day trial of any preferred injectable agent. Non-preferred agents require ninety (90) day trials of two (2) chemically unique preferred agents (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present.		
INTERFERONS[AP]		
AVONEX (interferon beta-1a) AVONEX PEN (interferon beta-1a) BETASERON (interferon beta-1b) REBIF (interferon beta-1a) REBIF REBIDOSE (interferon beta-1a)	EXTAVIA KIT (interferon beta-1b) EXTAVIA VIAL (interferon beta-1b) PLEGRIDY (peginterferon beta-1a)	
NON-INTERFERONS		
AUBAGIO (teriflunomide)* COPAXONE 20 mg (glatiramer) dalfampridine ER** dimethyl fumerate*** GILENYA (fingolimod) KESIMPTA INJECTION (ofatumumab)	AMPYRA (dalfampridine)** BAFIERTAM CAPSULES (monomethyl fumarate) COPAXONE 40 mg (glatiramer)**** glatiramer GLATOPA (glatiramer) MAVENCLAD (cladribine) MAYZENT (siponimod)***** PONVORY (ponesimod) TASCENSO ODT TABLETS (fingolimod lauryl sulfate) TECFIDERA (dimethyl fumarate)*** VUMERITY (diroximel) ZEPOSIA (ozanimod)	**In addition to class PA criteria, the following conditions and criteria may also apply:** *Aubagio requires the following additional criteria to be met: 1. Diagnosis of relapsing multiple sclerosis **and** 2. Measurement of transaminase and bilirubin levels within the (6) months before initiation of therapy and ALT levels at least monthly for six (6) months after initiation of therapy **and** 3. Complete blood cell count (CBC) within six (6) months before initiation of therapy **and** 4. Female patients must have a negative pregnancy test before initiation of therapy and be established on a reliable method of contraception if appropriate **and** 5. Patient is between eighteen (18) up to sixty-five (65) years of age **and** 6. Negative tuberculin skin test before initiation of therapy

		Dalfampridine ER and Ampyra require the following additional criteria to be met: 1. Diagnosis of multiple sclerosis **and 2. No history of seizures **and** 3. No evidence of moderate or severe renal impairment. ***Dimethyl fumerate and Tecfidera require the following additional criteria to be met: 1. Diagnosis of relapsing multiple sclerosis **and** 2. Complete blood count (CBC) within six (6) months of initiation of therapy and six (6) months after initiation **and** 3. Complete blood count (CBC) annually during therapy. ****Copaxone 40mg will only be authorized for documented injection site issues. *****Mayzent may be authorized with no additional requirement beyond the diagnosis for patients with documented secondary progressive MS. Kesimpta may be approved with documentation of treatment failure/inadequate treatment response after a 90-day trial of at least one preferred MS agent.

denotes change in current criteria
denotes new criteria

Belsomra

*Belsomra may be approved after a trial of zolpidem ~~and~~ or temazepam, unless one of the exceptions on the PA form is present.

SEDATIVE HYPNOTICS[AP]		
CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of all preferred agents in **BOTH** sub-classes before they will be approved, unless one (1) of the exceptions on the PA form is present. All agents except melatonin will be limited to fifteen (15) tablets in a thirty (30) day period. NOTE: WV Medicaid covers melatonin up to a maximum dose of 9 mg/day without a PA. Melatonin labeler code 51645 is preferred if available, however all NDCs are payable.		
BENZODIAZEPINES		
temazepam 15, 30 mg	estazolam flurazepam HALCION (triazolam) QUVIVIQ (daridorexant) RESTORIL (temazepam) temazepam 7.5, 22.5 mg triazolam	
OTHERS		
BELSOMRA (suvorexant)** melatonin ROZEREM (ramelteon) zolpidem 5, 10 mg	AMBIEN (zolpidem) AMBIEN CR (zolpidem) DAYVIGO (lemborexant) doxepin 3mg and 6mg EDLUAR (zolpidem) eszopiclone HETLIOZ (tasimelteon)[CL]* LUNESTA (eszopiclone) ramelteon SILENOR (doxepin) zaleplon zolpidem ER 6.25, 12.5 mg	For treatment naïve female patients, zolpidem and zolpidem ER maximum dosages will be limited to 5 mg and 6.25 mg respectively per day. *Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. **Belsomra may be approved after a trial of zolpidem and temazepam, unless one of the exceptions on the PA form is present.

denotes change in current criteria
denotes new criteria

Irritable bowel syndrome agents

All agents in this subclass require documentation of the current diagnosis. ~~and evidence that the patient has failed to find relief with dietary modification and a fourteen (14) day trial of an osmotic laxative.~~

IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS CL		
CLASS PA CRITERIA: All agents are approvable only for patients age eighteen (18) and older. **See below for additional sub-class criteria.**		
CONSTIPATION		
AMITIZA (lubiprostone) LINZESS 145 and 290 mcg (linaclotide) MOVANTIK (naloxegol) TRULANCE (plecanatide)	IBSRELA (tenapanor) LINZESS 72 mcg (linaclotide) lubiprostone capsule MOTEGRITY (prucalopride) RELISTOR INJECTION (methylnaltrexone) RELISTOR TABLET (methylnaltrexone) SYMPROIC (naldemedine)	All agents in this subclass require documentation of the current diagnosis. ~~and evidence that the patient has failed to find relief with dietary modification and a fourteen (14) day trial of an osmotic laxative.~~

		No agent shall be approved to treat opioid induced constipation (OIC) without evidence of at least 90-days of opioid use preceding the request. Continuation of coverage shall be granted with evidence of continuous and concurrent opioid use. **Agents may be authorized only for their FDA-approved labeled indication. The following agent-specific criteria shall also apply, unless one (1) of the exceptions on the PA form is present:** **Ibsrela** requires thirty (30) day trials of each preferred agent for IBS-C, however for males, a trial of Amitiza is not required. **Linzess 72mcg** may only be approved for a diagnosis of chronic idiopathic constipation (CIC) AND for those who cannot tolerate the 145mcg dose. **Lubiprostone** may only be authorized with a documented allergy or intolerance to Amitiza. **Motegrity** requires a 30-day trial of both Amitiza and Linzess. **Relistor** and **Symproic** are indicated for OIC and require thirty (30) day trials of both Movantik and Amitiza. **Trulance** requires thirty (30) day trials of both Amitiza and Linzess, however for the indication of IBS-C in males, a trial of Amitiza is not required. **Zelnorm** is indicated for females < 65 years of age diagnosed with irritable bowel syndrome with constipation (IBS-C) AND requires thirty (30) day trials of Amitiza and Linzess.