



denotes change in current criteria

denotes new criteria

Irritable Bowel Syndrome/Short Bowel Syndrome/Selected GI agents

Linzess 72 mcg:

Linzess 72mcg may only be approved for a diagnosis of chronic idiopathic constipation (CIC) AND for those who cannot tolerate the 145mcg dose.

Zelnorm:

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, unless otherwise ... (standard language).

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 LINZESS 72 mcg (linaclotide) AMITIZA (lubiprostone) All agents in this subclass require documentation of the MOVANTIK (naloxegol) MOTEGRITY (prucalopride) current diagnosis and evidence that the patient has failed to RELISTOR INJECTION (methylnaltrexone) LINZESS (linaclotide) find relief with dietary modification and a fourteen (14) day trial RELISTOR TABLET (methylnaltrexone) of an osmotic laxative. SYMPROIC (naldemedine) TRULANCE (plecanatide) 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: 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. Linzess 72mcg may only be app on (CIC) AND for those who orm is indicated for females < 65 years of age nosed with irritable bowel syndrome with ation (IBS-C) AND requires thirty (30) day trials iza and Linzess.





Spravato- update to existing criteria (addition of FDA approved diagnoses)

SPRAVATO[™] is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults or depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

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

1) Diagnosis of treatment resistant depression (TRD) <mark>or depressive symptoms in adults with major depressive</mark> disorder (MDD) with acute suicidal ideation or behavior by an identified psychiatrist; AND

2) Prescribed by a REMS-certified provider; AND

3) Age must be appropriate to the FDA-approved label; AND

4) Progress notes are required as documentation of the patient's diagnosis of treatment-resistant Major Depressive Disorder and must include screening to rule out Bipolar Disorder as well as all previous therapies failed; **AND**

5) The patient's baseline depression symptoms must be measured and documented using an objective clinical rating scale such as (but not limited to) the PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, or HAM-D; **AND**

6) Patient has failed to achieve a satisfactory response after attempting a minimum of THREE separate therapeutic trials for MDD. These trials must include antidepressants from at least two (2) different drug classes as well as at least one trial using augmentation therapy; **AND**

7) All medications must be taken compliantly for at least 8 weeks based on pharmacy fill history; AND

8) Spravato must be used in combination with an oral antidepressant.

Approvals will be for 90 days at a time.

CONTINUATION OF THERAPY CRITERIA

1) Patient's claims history must indicate concurrent use of an oral antidepressant; AND

2) Patient must show demonstrable improvement over baseline as measured by the same scale used for the initial approval.





Epidiolex update to existing criteria (addition of FDA approved diagnosis and age)

Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome or Tuberous Sclerosis Complex in patients 1 year of age and older.

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

1. Prescribed by or in consultation with a neurologist; AND

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

3. Documented diagnosis of Dravet Syndrome, Lennox Gastaut or Tuberous Sclerosis Complex; AND

4. For a diagnosis of Dravet Syndrome, patient must have failed to find satisfactory relief with trials of valproate and adjunctive clobazam; AND

5. For a diagnosis of Lennox-Gastaut Syndrome, patient must have failed adjunctive therapy with clobazam.

6. For a diagnosis of Tuberous Sclerosis complex, patient must have failed to find satisfactory relief with TWO antiepileptic drugs, at least one of which is preferred.

NOTE:

For a diagnosis of Dravet Syndrome, it is recommended that the patient should avoid carbamazepine, oxcarbazepine, esclicarbazepine, lamotrigine or phenytoin. For diagnosis of Lennox-Gastaut Syndrome carbamazepine should not be used. For diagnosis of Tuberous Sclerosis Complex associated with infantile spasms carbamazepine, oxcarbazepine or phenytoin should not be used.

Initial approval of Epidiolex will be for 90 days. Additional therapy shall be approved with documentation of satisfactory patient response.





VMAT 2 INHIBITORS

Ingrezza

INGREZZA is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia.

Initial* Prior Authorization Criteria:

- 1. Request must come from the treating neurologist or psychiatrist; AND
- 2. The patient must be within the age range as recommended by the FDA label; AND
- 3. Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; **AND**
- 4. Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT2 inhibitor; **AND**
- 5. Patient must provide a documented clinical diagnosis of tardive dyskinesia meeting DSM-V criteria including:
 - a. Involuntary athetoid or choreiform movements
 - b. History of treatment with a dopamine receptor blocking agent (DRBA) such as an antipsychotic or metoclopramide
 - c. Symptom duration lasting at least 8 weeks
 - AND
- Prescriber must provide a brief description of the medical necessity of therapy by documenting all target symptoms and their impact on the patient's function and activities of daily living; AND
- 7. Prescriber must submit the results of an Abnormal Involuntary Movement Scale (AIMS) exam with every request for prior authorization of Ingrezza; **AND**
- 8. Prescriber must submit documentation of all other therapies attempted and their associated benefit (including relevant AIMS scores).

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

We will want to watch utilization, for possible revisiting by the DUR board.





<u>Austedo</u>

AUSTEDO is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with chorea associated with Huntington's disease and for the treatment of tardive dyskinesia in adults.

Initial* Prior Authorization Criteria:

- The patient must be within the age range as recommended by the FDA label; AND
- Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; AND
- Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT2 inhibitor
- Prescriber must provide a brief description of the medical necessity of therapy by documenting all target symptoms and their impact on the patient's function and activities of daily living; AND

The following indication-specific criteria also apply:

- I. Treatment of Chorea associated with Huntington's Disease:
 - 1. Request must come from the treating neurologist; AND
 - 2. All previous therapies must be documented along with their relative benefit. Unless contraindicated, the patient must have a documented 90-day trial of **amantadine** or **Xenazine (tetrabenazine)**.
- II. Treatment of Tardive Dyskinesia (TD):
 - 1. Request must come from the treating neurologist or psychiatrist; AND
 - 2. Patient must provide a documented clinical diagnosis of tardive dyskinesia meeting DSM-V criteria including:
 - d. Involuntary athetoid or choreiform movements
 - e. History of treatment with a dopamine receptor blocking agent (DRBA) such as an antipsychotic or metoclopramide
 - f. Symptom duration lasting at least 8 weeks

AND

3. Prescriber must submit the results of an Abnormal Involuntary Movement Scale (AIMS) exam with every request for prior authorization of Austedo; **AND**





4. Prescriber must submit documentation of all other therapies attempted and their associated benefit (including relevant AIMS scores).

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

We will want to watch utilization, for possible revisiting by the DUR board.





Office of Pharmacy Services Prior Authorization Criteria Effective 12/1/2020 Benlysta[®] (Belimumab)

Benlysta is indicated for the treatment of adults and children \geq 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy.

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

1. Documented diagnosis of active systemic lupus erythematosus (SLE); AND

2. The patient is positive for autoantibodies (anti-nuclear antibody (ANA) and anti-double-stranded DNA (anti-dsDNA); **AND**

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

3. Prescribed by, or in consultation with, a rheumatologist; AND

4. The patient has had a documented inadequate response or intolerance to at least **TWO** of the following agents: non-steroidal anti-inflammatory drugs (NSAIDS), hydroxychloroquine, corticosteroids, methotrexate, azathioprine, cyclosporine, or mycophenolate.

Initial approval will be granted for 3 months.

NOTE: Use is not recommended in patients with severe active lupus nephritis, severe active CNS lupus, or in combination with other biologics, including B-cell targeted therapies or IV cyclophosphamide. Use of Benlysta should be avoided and is not recommended in these situations.

CONTINUATION OF THERAPY CRITERIA:

Clinical documentation must be submitted documenting stability/reduction in disease activity OR a reduction in corticosteroid dose.





Cytokine/CAM antagonists - (Taltz now preferred, Cosentyx is NP, Xeljanz preferred for UC/RA)

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of both Humira and Enbrel unless one (1) of the exceptions on the PA form is present. For FDA-approved indications, an additional ninety (90) day trial of Cosentyx will also be required. 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

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.

*Cosentyx will be authorized for treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis only after inadequate response to a ninety (90) day trial of Humira or Enbrel.

*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 Humira or Enbrel.

**Xeljanz will only be preferred for the treatment of rheumatoid arthritis and ulcerative colitis. For all other indications it is non-preferred. Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

- Ankylosing spondylitis, Plague Psoriasis and Psoriatic Arthritis:
 - Plaque psoriasis: Preferred agents require evidence of failure after at least 90 days of 0 topical therapy* with two different agents classified as an emollient, corticosteroid, topical retinoid or vitamin D analog. A 90-day trial of one DMARD (or a systemic retinoid such as acitretin) is also required.

* Topical therapy requirement is waived for moderate-to-severe disease affecting at least 5% of the BSA or crucial body areas such as the hands, feet, face, neck, genitals/groin, or intertriginous areas. Psoriatic Arthritis: Preferred agents require a 90-day trial of one DMARD.

- 0 **Ankylosing Spondylitis:** Preferred agents require failure of two 30-day trials of NSAIDs. 0
- Note: Taltz may be authorized only after a 90-day trial of either Humira or Enbrel.
- 0
- Non-preferred agents require 90-day trials of Enbrel, Humira and Taltz. 0 0
- **Rheumatoid arthritis:**
 - Humira, Enbrel and Xeljanz each require a 90-day trial a DMARD. 0
 - Non-preferred agents require 90-day trials each of one DMARD, and Enbrel, Humira and 0 Xeljanz.
- **Ulcerative Colitis:**
 - Humira and Xeljanz may be authorized upon demonstration of an inadequate response to at 0 least a thirty (30) day course of aminosalicylates (e.g. sulfasalazine, mesalamine) requiring treatment for two (2) or more exacerbations using corticosteroids, such as prednisone.





 In addition to the above criteria, non-preferred agents require a 90-day trial of Humira and Xeljanz.





MABS/ ANTI- IL/IgE

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 <u>PA Criteria</u> page by clicking the hyperlink.

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Onfi/Diacomit

***Diacomit may only be approved as adjunctive therapy for diagnosis of Dravet Syndrome when prescribed by, or in consultation with, a neurologist AND requires a thirty (30) day trial of valproate and clobazam unless one (1) of the exceptions on the PA form is present. Diacomit must be used concurrently with clobazam.

*Onfi shall be authorized as adjunctive therapy for treatment of Lennox-Gastaut Syndrome without further restrictions. Off-label use requires an appeal to the Medical Director. NOTE: generic clobazam is preferred over brand ONFI.

*Onfi shall be authorized as adjunctive therapy for treatment of Lennox-Gastaut Syndrome and Dravet Syndrome without further restrictions. All other indications require an appeal to the Medical Director. NOTE: generic clobazam is preferred over brand ONFI.

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.

carbamazepine carbamazepine ER carbamazepine XR divalproex divalproex ER divalproex sprinkle EPITOL (carbamazepine) GABITRIL (tiagabine) lamotrigine levetiracetam IR levetiracetam ER levetiracetam ER levetiracetam EN
2
levetiracetam IR suspension
oxcarbazepine suspension and tablets
TEGRETOL SUSPENSION (carbamazepine)
topiramate IR
topiramate ER*
valproic acid
VIMPAT (lacosamide)
zonisamide
zonsaniao

ADJUVANTS APTIOM (eslicarbazepine)

BANZEL (rufinamide)

carbamazepine XR CARBATROL (carbamazepine) DEPAKENE (valproic acid)

(stripentol)***

FELBATOL (felbamate) FYCOMPA (perampanel) KEPPRA (levetiracetam) KEPPRA SOLUTION (levetiracetam) KEPPRA XR (levetiracetam)

LAMICTAL (lamotrigine)

clobazam*

felbamate

BRIVIACT (brivaracetam) carbamazepine oral suspension

DEPAKOTE (divalproex)

DEPAKOTE ER (divalproex)

EQUETRO (carbamazepine) FANATREX SUSPENSION (gabapentin)

DEPAKOTE SPRINKLE (divalproex)

DIACOMIT CAPSULE/POWDER PACK

LAMICTAL CHEWABLE (lamotrigine) LAMICTAL ODT (lamotrigine) *Topiramate ER will be authorized after a thirty (30) day trial of topiramate IR.

**Qudexy XR and Trokendi XR are only approvable on appeal.

***Diacomit may only be approved as adjunctive therapy for diagnosis of Dravet Syndrome when prescribed by, or in consultation with, a neurologist AND requires a thirty (30) day trial of valproate and clobazam unless one (1) of the exceptions on the PA form is present. Diacomit must be used concurrently with clobazam.

BENZODIAZEPINESAP

clonazepam ODT DIASTAT (diazepam rectal) KLONOPIN (clonazepam) ONFI (clobazam)* ONFI SUSPENSION (clobazam)* SYMPAZAN (clobazam film)* *Onfi shall be authorized as adjunctive therapy for treatment of Lennox-Gastaut Syndrome and Dravet Syndrome without further restrictions. All other indications require an appeal to the Medical Director. NOTE: generic clobazam is preferred over brand ONFI.





SGLT2 Inhibitors

*Preferred SGLT2 inhibitors and combinations may be approved for a diagnosis of Heart Failure with Reduced Ejection Fraction (HFrEF) with or without Type II DM, Chronic Kidney Disease (CKD) with or without Type II DM, or Type II DM with Atherosclerotic Cardiovascular Disease (ASCVD) without further restrictions.

HYPOGLYCEMICS, SGLT2 INHIBITORSCL

CLASS PA CRITERIA: Non-preferred agents will only be approved (in 6-month intervals) if ALL of the following criteria has been met:

- 1) Current A1C must be submitted. Agents in this class will not be approved for patients with a starting A1C of less than (<) 7%.
- Documentation demonstrating 90 days of compliance <u>on all current diabetic therapies</u> is provided.
 Documentation demonstrating treatment failure with all unique preferred agents in the same class.

Re-authorizations will require documentation of continued compliance on all diabetic therapies and A1C levels must reach goal, (either an A1C of <8%, or demonstrated continued improvement).

	SGLT2 INHIBITORS	
FARXIGA (dapagliflozin)* INVOKANA (canagliflozin)* JARDIANCE (empagliflozin)*	STEGLATRO (ertugliflozin)	*Preferred SGLT2 inhibitors and combinations may be approved for a diagnosis of Type II DM along with Heart Failure with Reduced Ejection Fraction (HFrEF), Chronic Kidney Disease (CKD) or Atherosclerotic Cardiovascular Disease (ASCVD) without further restrictions
	SGLT2 COMBINATIONS	
INVOKAMET (canagliflozin/ <u>metformin)*</u> SYNJARDY (empagliflozin/ <u>metformin)*</u>	GLYXAMBI (empagliflozin/linagliptin) INVOKAMET XR (canagliflozin/metformin) SEGLUROMET (ertugliflozin/metformin STEGLUJAN (ertugliflozin/sitagliptin) SYNJARDY XR (empagliflozin/metformin) TRIARDY XR	





Office of Pharmacy Services Prior Authorization Criteria Effective 12/1/2020 Nexletol[®], Nexlizet[®] (bempedoic acid, bempedoic acid/ezetimibe)

Nexletol[®] (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Nexlizet[®] contains the active ingredient bempedoic acid, in combination with ezetimibe, a cholesterol absorption inhibitor.

CRITERIA FOR APPROVAL:

- 1) Patient must meet all age and indication restrictions imposed by the current FDAapproved label; **AND**
- 2) Documentation must be submitted indicating that the patient failed to reach an LDL<70 mg/dL after an 8-week trial of either atorvastatin 40 80 mg + ezetimibe OR rosuvastatin 20 40 mg + ezetimibe. Note: If the patient failed to tolerate the first statin, then they must be trialed on the second statin for 8-weeks or until intolerance occurs.</p>

A request for Bempedoic acid or Bempedoic acid/Ezetimibe in combination with a PCSK9 inhibitor will only be authorized after review by medical director.

Initial approval will be for 90 days.

Additional coverage may be granted with documentation of efficacy supported by lipid panel showing a reduction of at least 10% in LDL-C compared to pre-treatment levels.





CGRP Receptor Antagonists (prophylaxis)

. Full PA criteria may be found on the <u>PA Criteria</u> page by clicking the hyperlink. Non-preferred agents require a 90-day trial of all preferred agents.

. Full PA criteria may be found on the <u>PA Criteria</u> page by clicking the hyperlink. Nonpreferred agents require a 90-day trial of all preferred agents. All currently established regimens may be grandfathered with documentation of efficacy and adherence to therapy.

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	ANTIMIGRAINE AGENTS, PROPHY			
	CLASS PA CRITERIA: All agents require a p agents require a 90-day trial of all preferred agen	arior authorization. Full PA criteria may be for	ound on the PA Criteria page by clic	king the hyperlink. Non-preferred
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	PREFERRED AGENTS	NON-PREFERRED AGENTS		RITERIA
	PREFERRED AGENTS AIMOVIG (erenumab) AJOVY (fremanezumab)	NON-PREFERRED AGENTS EMGALITY (galcanezumab) 120mg/mL EMGALITY (galcanezumab) 300mg/3 mL*		equires review by the Medical

AIMOVIG, EMGALITY and AJOVY are calcitonin gene-related peptide receptor antagonists indicated for the preventive treatment of migraine in adults.

- Emgality 300 mg/3 mL requires review by the Medical Director and is available only on appeal.
- Emgality is a non-preferred agent and requires a 90-day trial of both Aimovig and Ajovy.

Prior authorization requests for Aimovig or Ajovy may be approved if the following criteria are met.

- 1. The patient is within the age range as recommended by the FDA label; AND
- 2. Prescriber is a specialist or has consulted a specialist such as a neurologist; AND
- 3. Documentation is provided that MIDAS or HIT-6 assessment testing has been taken at baseline; **AND**





- 4. Patient is experiencing at least 4 migraine days per month requiring acute pharmacological management; **AND**
- 5. Patient has failed to achieve therapeutic goals after using an agent from at least <u>TWO</u> of the following three classes of preventative medications. Individual trials may be waived when evidence is presented indicating a direct contraindication exists due to a clinically significant allergy, drug interaction or adverse effect. To qualify as a trial, each agent must be dosed within the listed range for at least 90 consecutive days. Agents may be used alone or in combination, however at least one of these preventative trials must have taken place in the last 12 months.
 - **Beta Blockers** metoprolol (50 200 mg daily), propranolol (40-160 mg daily), timolol (10-30 mg daily), nadolol (20-240 mg daily), atenolol (25-100 mg daily)
 - Antidepressants amitriptyline (20-50 mg qHS), venlafaxine (75-150 mg daily)
 - Anticonvulsants valproate (500-1500 mg daily), topiramate (100 mg daily)

For agents not listed above, a prophylactic trial may be satisfactory only when the request is accompanied by documentation referencing clinical trials that support the agent's efficacy in migraine prevention.

Initial prior authorization approval will be for 3 months. Additional therapy may be approved only with clinical documentation showing a 50% reduction in either the number of headache days per month or the overall symptom severity (as measured by MIDAS or HIT-6) compared to baseline.