

Pharmacy Medical Policy Drug Management & Retail Pharmacy Prior Authorization Policy

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Policy Number: 049

BCBSA Reference Number: None

Related Policies

 Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy, #621A

Information Pertaining to All Policies

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

 Prior Authorization Step Therapy Quality Care Dosing 		Pharmacy Operation Tel: 1-800-366-7778 Fax: 1-800-583-6289 Policy last updated	
Pharmacy (Rx) or Medical (MED) benefit coverage	⊠ Rx □ MED	To request for coverage: Providers may call, fax, or mail the attached form (<u>Formulary Exception/Prior</u> <u>Authorization form</u>) to the address below.	
 Policy applies to Commercial Members: Managed Care (HMO and POS), PPO and Indemnity MEDEX with Rx plan Managed Major Medical with Custom BCBSMA Formulary Comprehensive Managed Major Medical with Custom BCBSMA Formulary Managed Blue for Seniors with Custom BCBSMA Formulary 		Pharmacy Operation 25 Technology Place Hingham, MA 02043 Individual Consider	e a tion: Policy for requests that riteria of this policy, see section

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Standard Formulary	
Drug	Formulary Status
Aqneursa ™ (levacetylleucine)	PA Required
Arikayce [®] (amikacin)	PA Required
Attruby ™ (acoramidis)	PA Required
bexarotene gel	PA Required
Bylvay ™ (odevixibat)	PA Required
Daybue ™ (trofinetide)	PA Required
Dojolvi ™ (triheptanoin)	PA Required
Duvyzat ™(givinostat)	PA Required
Eohilia ™ (budesonide)	PA Required
Filspari ™ (sparsentan)	PA Required
Firdapse [®] (amifampridine)	PA Required
lqirvo ® (elafibranor)	PA Required
Isturisa [®] (osilodrostat)	PA Required
Joenja ® (leniolisib)	PA Required
Livdelzi [®] (seladelpar)	PA Required
Livmarli ™ (maralixibat)	PA Required
Litfulo ™ (ritlecitinib)	PA Required
Miplyffa ™ (arimoclomol)	PA Required

Drug	Formulary Status
Orladeyo ™ (berotralstat)	PA Required
Oxervate ™ (cenegermin)	PA Required
Pyrukynd [®] (mitapivat)	PA Required
Recorlev [®] (levoketoconazole)	PA Required
Skyclarys ™ (omaveloxolone)	PA Required
Sohonos ™ (palovarotene)	PA Required
Targretin [®] Gel (bexarotene)	PA Required
Tarpeyo ™ (budesonide)	PA Required
Tavneos ™ (avacopan)	PA Required
Viberzi [®] (eluxadoline)	PA Required
Vijoice ™ (alpelisib)	PA Required
Vivjoa ™ (oteseconazole)	PA Required
Voxzogo ™ (vosoritide)	PA Required
Vyndaqel [®] (tafamidis meglumine)	PA Required
Vyndamax ® (tafamidis)	PA Required
Xifaxan [®] (rifaximin)	PA Required
Xolremdi ™ (mavorixafor)	PA Required
Zokinvy [®] (Ionafarnib)	PA Required

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We may cover Aqneursa [™]** (Levacetylleucine) for the treatment of Niemann-Pick disease type C (NPC) when ALL of the following criteria are met:

Patient weights at least 33 pounds or 15 kg, AND

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- Patient is not using Miplyffa (arimoclomol) in combination with Aqneursa, AND
 - Diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating one of the following: • Mutations in both alleles of NPC1 or NPC2 OR
 - Mutation in one allele AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2× ULN)

We may cover Arikayce ^{®**} (amikacin suspension) for the treatment of adults, who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease when ALL of the following criteria are met:

- Diagnosis of Mycobacterium avium complex (MAC) lung disease, AND
- Minimum of 6 consecutive months of a multidrug background regimen therapy, AND
- The drug is prescribed by a board-certified or board eligible Pulmonologist, or an Infectious Disease Specialist

We may cover Attruby ^{™**} (acoramidis) for the treatment of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) when ALL of the following criteria are met:

- Diagnosis of ATTR-CM, including ATTRwt or hATTR, confirmed by one of the following:
 - Bone scintigraphy
 - Endomyocardial biopsy
 - For patients with hATTR, genetic testing,

AND

- Age is equal to or greater than 18 years, AND
- Patient does not have NYHA Class IV HF at the time of initial request, AND
- The drug is prescribed by a board-certified or board eligible cardiologist, AND
- Attruby is not prescribed in combination with Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Onpattro (patisiran) or Amvuttra (vutrisiran)

We may cover Bylvay ^{™**} (odevixibat) for the treatment of pruritus when ALL of the following criteria are met:

- Age is greater than or equal to three (3) months, AND
- Confirmed diagnosis of progressive familial intrahepatic cholestasis (PFIC) with molecular genetic testing, **AND**
- Molecular genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3, AND
- Presence of moderate to severe pruritis, AND
- Drug-induced pruritus has been ruled out, AND
- No history of liver transplant, **AND**
- No history of biliary diversion surgery within the past 6 months, AND
- No clinical evidence of decompensated cirrhosis

OR

- Age is greater than or equal to twelve (12) months, AND
- Confirmed diagnosis of Alagille syndrome (ALGS), AND
- For the treatment of cholestatic pruritus

We may cover Daybue ^{™**} (trofinetide) for the treatment of Rett syndrome when ALL of the following criteria are met:

- · diagnosis of Rett syndrome (mutations in MECP2 are not universal), AND
- Age is equal to or greater than 2 years

Note: If approved the Prior Authorization will be granted for up to one (1) year.

We may cover Dojolvi [™]** (triheptanoin) for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD) when **ALL** of the following criteria are met:

- molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD), AND
- The drug is prescribed by a board-certified or board eligible Endocrinologist, or a board-certified or board eligible Geneticist, **AND**
- Frequent severe major medical episodes of hypoglycemia, rhabdomyolysis, or exacerbation of cardiomyopathy requiring emergency room visits, acute care visits, or hospitalizations **OR** Severe susceptibility to hypoglycemia or recurrent symptomatic hypoglycemia requiring intervention

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We may cover Duvyzat [™]** (givinostat) for the treatment of Duchenne muscular dystrophy (DMD) when ALL of the following criteria are met:

- Age is equal to or greater than 6 years, AND
- Genetically confirmed diagnosis of Duchenne muscular dystrophy (DMD), AND
- Patient is ambulatory upon initiation of therapy, AND
- Patient is stable on baseline corticosteroids for 6 months, AND
- The drug is prescribed by a board-certified or board eligible specialist (e.g. neurologist) with experience in the treatment of DMD

We may cover Eohilia [™]** (budesonide) for eosinophilic esophagitis (EoE) when ALL of the following criteria are met:

- Age is equal to or greater than 11 years, AND
- Documentation of Diagnosis of eosinophilic esophagitis (EoE), AND
- Four (4) or more episodes of dysphagia in a two (2) week period.

We may cover Filspari [™]** (sparsentan) for the treatment of Primary Immunoglobulin A nephropathy (IgAN) when ALL of the following criteria are met:

- Age is equal to or greater than 18 years, **AND**
- Diagnosis of biopsy verified Primary Immunoglobulin A nephropathy (IgAN).

We may cover Firdapse ^{®**} (amifampridine) for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) when **ALL** of the following criteria are met:

- Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS), AND
- Age is equal to or greater than 6 years

Note: If approved the Prior Authorization will be granted for up to one (1) year.

We may cover lqirvo [®] (elafibranor) for primary biliary cholangitis (PBC) when ALL of the following criteria are met:

- Age is equal to or greater than 18 years, **AND**
- Diagnosis of PBC confirmed by two (2) of the following:
 - Biochemical evidence of cholestasis based on alkaline phosphatase (ALP) elevation (as defined by the performing laboratory's reference values)
 - Presence of antimitochondrial antibody (AMA), or other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
 - Histologic evidence of PBC seen on biopsy

AND

- Inadequate response for at least 12 months to ursodeoxycholic acid (UDCA) [recommended dose is 13–15 mg/kg/day] or intolerance to UDCA, AND
- Member does not have decompensated cirrhosis, AND
- The drug is prescribed by a board-certified or board eligible gastroenterologist or a board-certified or board eligible hepatologist, **AND**
- Not used in combination with Ocaliva [®] (obeticholic acid) or Livdelzi [®] (seladelpar)

We may cover Isturisa ^{®**} (osilodrostat) for the treatment of adults for the treatment of Cushing's Disease when ALL of the following criteria are met:

- Age is equal to or greater than 18 years, AND
- Confirmed documented diagnosis of Cushing's disease (NOT Cushing's Syndrome), AND
- The drug is prescribed by a board-certified or board eligible endocrinologist, AND
- Documentation of failed pituitary surgery or contraindication to pituitary surgery, AND
- Prescriber attests to the monitoring of Cortisol levels during titration and maintenance phase to ensure appropriate dose and adequate clinical response, **AND**
- This medication is not FDA approved for the treatment of Cushing's Syndrome.

We may cover Joenja ^{®**} (leniolisib) for activated phosphoinositide 3-kinase delta (PI3K δ) syndrome (APDS) when **ALL** of the following criteria are met:

- Age is equal to or greater than 12 years, AND
- Documented APDS/PASLI-associated PIK3CD/PIK3R1 mutation without concurrent use of immunosuppressive medication

We may cover Livdelzi[®] (seladelpar) for primary biliary cholangitis (PBC) when ALL of the following criteria are met:

- Age is equal to or greater than 18 years, AND
- Diagnosis of PBC confirmed by two (2) of the following:
 - Biochemical evidence of cholestasis based on alkaline phosphatase (ALP) elevation (as defined by the performing laboratory's reference values)
 - Presence of antimitochondrial antibody (AMA), or other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
 - Histologic evidence of PBC seen on biopsy

AND

- Inadequate response for at least 12 months to ursodeoxycholic acid (UDCA) [recommended dose is 13–15 mg/kg/day] or intolerance to UDCA, AND
- Member does not have decompensated cirrhosis, AND
- The drug is prescribed by a board-certified or board eligible gastroenterologist or a board-certified or board eligible hepatologist, **AND**
- Not used in combination with Ocaliva [®] (obeticholic acid) or Iqirvo [®] (elafibranor)

We may cover Livmarli [™]** (maralixibat) for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) when ALL of the following criteria are met:

- Age is equal to or greater than 3 months of age, AND
- Confirmed documented diagnosis of Alagille Syndrome (ALGS), AND
- Presence of moderate to severe pruritis, AND
- Does not have chronic diarrhea requiring ongoing intravenous fluid or nutritional intervention, AND
- No history of liver transplant, **AND**
- No history of surgical interruption of enterohepatic circulation (for example, partial external biliary diversion [PEBD] surgery), AND
- No clinical evidence of decompensated cirrhosis

OR

- Age is equal to or greater than 12 months of age, AND
- Confirmed documented diagnosis of progressive familial intrahepatic cholestasis (PFIC), AND
- Does not have PFIC type 2 with specific ABCB11 variants.

We may cover Litfulo [™]** (ritlecitinib) for the treatment of severe alopecia areata when ALL of the following criteria are met:

- Age is equal to or greater than 12 years of age, **AND**
- Confirmed diagnosis of alopecia areata
- Documentation of ≥50% scalp hair loss
- Note: If approved the Prior Authorization will be granted for up to one (1) year

We may cover Miplyffa [™]** (arimoclomol) for the treatment of Niemann-Pick disease type C (NPC) when ALL of the following criteria are met:

• Patient is at least 2 years of age, **AND**

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- Patient is not using Aqneursa (Levacetylleucine) in combination with Miplyffa, AND
 - Diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating one of the following: • Mutations in both alleles of NPC1 or NPC2 OR
 - Mutation in one allele AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2× ULN)

We may cover Orladeyo [™]** (berotralstat) for prophylaxis to prevent attacks of hereditary angioedema (HAE)

- Age is equal to or greater than 12 years, AND
- Diagnosis of hereditary angioedema (HAE), AND
- The drug is prescribed by a board-certified or board eligible Allergy & Immunology, Geneticist, or a Physician which specializes in the treatment of hereditary angioedema (HAE), **AND**
- Being used for the prevention of HAE attacks

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We may cover Oxervate [™]** (cenegermin) eye drops for the treatment of adults with neurotrophic keratitis when ALL of the following criteria are met:

- Diagnosis of neurotrophic keratitis, AND
- The approval is given for Eight (8) weeks of treatment

Note: If approved the Prior Authorization will be limited to one (1) course of an 8-week treatment per the FDA label.

We may cover Pyrukynd ^{®**} (mitapivat) for the treatment of adults with pyruvate kinase (PK) deficiency when **ALL** of the following criteria are met:

- Diagnosis of pyruvate kinase (PK) deficiency, AND
- Patient has at least two mutant alleles in the PKLR gene, of which at least one is a missense mutation.

We may cover Recorlev ®** (levoketoconazole) when ALL of the following criteria must be met:

- The patient has hypercortisolemia and confirmed Cushing's syndrome, AND
- The patient is \geq 18 years old, **AND**
- The patient has had surgery, and it was not curative or surgery is contraindicated, AND
- Documentation of baseline urinary free cortisol, AND
- Documentation of baseline live enzyme function tests

We may cover Rezdiffra ^{™**} (resmetirom) when ALL of the following criteria must be met:

- The patient has documented diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) previously known as noncirrhotic nonalcoholic steatohepatitis (NASH), **AND**
- The patient is \geq 18 years old, **AND**
- For patients with BMI >27, require a trial of lifestyle interventions for at least 3 months, with a goal of at least 5% to 10% weight loss, before authorizing Rezdiffra, **AND**
- The drug is prescribed by a board-certified or board eligible Gastroenterologist, or Hepatologist.

We may cover Skyclarys ^{™**} (omaveloxolone) for the treatment of Friedreich's ataxia when **ALL** of the following criteria must be met:

- The patient has a genetically confirmed diagnosis of Friedreich's Ataxia, AND
- The patient is \geq 16 years old, **AND**
- The drug is prescribed by a board-certified or board eligible Neurologist.

We may cover Sohonos [™]** (palovarotene) for the treatment of Fibrodysplasia Ossificans Progressiva (FOP) when ALL of the following criteria must be met:

- The patient has a genetically (ACVR1) confirmed diagnosis of Fibrodysplasia Ossificans Progressiva (aka Myositis Ossificans Progressiva or Stoneman disease), **AND**
- The patient is born male ≥ 10 years old **OR** born female ≥ 8 years old, **AND**
- The drug is prescribed by a specialist in rare connective tissue diseases.

We may cover Targretin [®]** (bexarotene) OR Bexarotene Gel for the topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma (CTCL) when ALL of the following criteria are met:

- Diagnosis of refractory or persistent cutaneous T-cell lymphoma (CTCL), AND
- The Member has Stage IA or IB, AND
- Document previous other therapies or a clinical rational for not using other therapies.

We may cover Tarpeyo ^{™**} (budesonide) to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) when **ALL** of the following criteria are met:

- Age is equal to or greater than 18 years, **AND**
- Diagnosis of primary immunoglobulin A nephropathy (IgAN), AND
- Document urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

We may cover Tavneos ^{™**} (avacopan) for adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) when ALL of the following criteria are met:

- Age is equal to or greater than 18 years, AND
- Diagnosis of granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA], AND
- Used with glucocorticoids as part of standard therapy

Note: If approved the Prior Authorization will be granted for up to one (1) year.

We may cover Viberzi ^{®**} (eluxadoline) for the treatment of irritable bowel syndrome with diarrhea (IBS-D) when **all** of the following criteria are met:

- Age is equal to or greater than 18 years, AND
- Diagnosis of irritable bowel syndrome with diarrhea (IBS-D).

We may cover Vijoice ^{™**} (avacopan) for patients with with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) when **ALL** of the following criteria are met:

- Age is equal to or greater than two (2) years, AND
- Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS), AND
- Patient requires systemic therapy.

We may cover Vivjoa ^{™**} (oteseconazole) for patients with recurrent vulvovaginal candidiasis (RVVC) with a history of RVVC which are NOT of reproductive potential when **all** of the following criteria are met:

- Age is equal to or greater than 12 years, AND
- Diagnosis of recurrent vulvovaginal candidiasis (RVVC), AND
- Patient has a history of RVVC (≥3 acute VVC episodes within 12 months), AND
- Patient is not of reproductive potential (i.e., history of tubal ligation, salpingo-oophorectomy, hysterectomy, or postmenopausal)

Note: If approved the Prior Authorization will be granted for up to one (1) year.

We may cover Voxzogo ^{™**} (vosoritide) for pediatric patients with achondroplasia when **ALL** of the following criteria are met:

- Age is greater than or equal to 4 months of age, AND
- Diagnosis of achondroplasia, AND
- Confirmed open epiphyses.

We may cover Vyndaqel [®]** (tafamidis meglumine) or Vyndamax [®]** (tafamidis) when the patient has met ALL of the below criteria:

- Patient has a confirmed Diagnosis of Wild-type ATTR Amyloidosis (ATTR) OR hereditary transthyretin-mediated amyloidosis (ATTR), AND
- Patient is being treated for cardiomyopathy, AND
- Age is equal to or greater than 18 years

We may cover Xdemvy [™]** (lotilaner) for the treatment of Demodex blepharitis when ALL of the following criteria are met:

- Confirmed diagnosis of Demodex blepharitis, AND
- The drug is prescribed by a board-certified or board eligible optometrist or ophthalmologist or an Infectious Disease Specialist

We may cover **Xifaxan**^{®**} (rifaximin) when the patient has met **ALL** of the below criteria:

- Patient has a confirmed Diagnosis of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia Coli, **AND**
- Age is equal to or greater than 12 years.
- OR
- Patient has a confirmed diagnosis of irritable bowel syndrome with Diarrhea (IBS-D) **or** Small Intestinal Bacterial Overgrowth (SIBO), **AND**
- Age is equal to or greater than 18 years.

OR

- Patient is trying to reduce the risk of overt hepatic encephalopathy (HE) recurrence, AND
- Age is equal to or greater than 18 years.

Note: If approved the Prior Authorization will be granted for up to one (1) year.

We may cover Xolremdi [™]** (mavorixafor) for pediatric patients with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) when **ALL** of the following criteria are met:

- Age is equal to or greater than 12 years of age, AND
- Confirmed diagnosis of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis), AND
- Documentation of baseline absolute neutrophil count (ANC) and absolute lymphocyte count (ALC) unless this is a reauthorization where the documentation would be current.

We may cover Zokinvy ®** (Ionafarnib) when the patient has met ALL of the below criteria:

- Confirmed diagnosis of one (1) of the following:
 - Hutchinson-Gilford progeria syndrome (HGPS)
 - o Heterozygous LMNA mutation with progerin-like protein accumulation
 - Homozygous or compound heterozygous ZMPSTE24 mutations

AND

- Patient has a BSA of at least 0.39 m², AND
- Age is equal to or greater than 12 months of age, AND
- Requested dose is appropriate for patient's BSA.

Note: If approved the Prior Authorization will be granted for up to one (1) year.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

For non-formulary/non-covered medications, requests must meet criteria above and the member must have had a previous treatment failure with or a contraindication to two covered formulary alternatives when available.

We do not cover the medications listed above for other conditions not listed above.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Individual Consideration

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements.
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable.
- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service[®] Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex[®]; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department 25 Technology Place Hingham, MA 02043 Phone: 1-800-366-7778 Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
7/2025	Updated Orladeyo criteria, added Xdemvy [™] to the policy.
3/2025	Updated to add Aqneursa ™, Attruby ™ and Miplyffa ™ to the policy.
2/2025	Updated to add Iqirvo [®] and Livdelzi [®] to the policy.
1/2025	Update to add Viberzi [®] to the policy and to apply full FDA approval Filspari label to the criteria.
9/2024	Updated to add Xolremdi [™] and Duvyzat [™] to the policy and to update the new age limit for Livmarli [®]
8/2024	Updated to add new indication for Livmarli [®] And clarified Tarpeyo [™] criteria and updated age for Voxzogo [™] .

7/2024	Updated to add Rezdiffra ™ to the policy.
5/2024	Updated to add Rezultina to the policy.
1/2024	Updated to add Sohonos ™ to the policy.
10/2023	
	Updated to add Litfulo ™ to the policy.
9/2023	Updated IC to align with 118E MGL § 51A.
7/2023	Updated Age for Livmarli ™ and clarified Xifaxan [®] coding and added Filspari ™,
	Skyclarys ™, Daybue ™, and Joenja [®] to the policy.
4/2023	Updated age for Firdapse [®] .
1/2023	Updated to add Vijoice [™] and Xifaxan to the policy.
8/2022	Updated to add Bexarotene Gel to the policy
7/2022	Updated to add Pyrukynd to the policy.
4/2022	Updated to move Rinvoq [®] to Step policy 010 and to add Recorlev [®] .
2/2022	Updated to add Tarpeyo [™] , Tavneos [™] , Rinvoq [®] , and Voxzogo [™] to the policy.
1/2022	Updated to add Livmarli [™] to the policy.
10/2021	Updated to add Bylvay [™] to the policy.
4/2021	Updated to add Zokinvy [®] to the policy.
2/2021	Updated to add Orladeyo [™] to the policy.
10/2020	Updated to add Dojolvi ™ to the policy.
10/2020	Updated to add Targretin Gel to the policy.
9/2020	Updated to add Isturisa [®] to the policy.
10/2019	Updated to add Vyndaqel ® & Vyndamax ®
8/2019	Updated to add Firdapse [®] to the policy.
7/2019	Updated to add Oxervate [™] to the policy.
4/2019	Implementation of a new policy with a new to market medication Arikayce ${ m I}$

References

- 1. Arikayce ® [package insert]. Bridgewater, NJ: Insmed, Inc.: 9/2018.
- 2. Oxervate [™] [package insert]. Boston, MA: Dompé U.S. Inc.: 11/2018.
- 3. Firdapse [®] [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.: 11/2018.
- 4. Vyndaqel [®] & Vyndamax [®] [package insert]. New York, NY: Pfizer, Inc.: 8/2019.
- 5. Isturisa [®] [package insert]. Lebanon, NJ: Recordati Rare Disease, Inc.: 3/2020.
- 6. Targretin [®] Gel [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals: 10/2016.
- 7. Dojolvi ™ [package insert]. Novato, CA: Ultragenyx Pharmaceutical Inc.: 6/2020.
- 8. Orladeyo [™] [package insert]. Durham, NC: BioCryst Pharmaceuticals, Inc.: 12/2020.
- 9. Zokinvy ™ [package insert]. Palo Alto, CA: Eiger BioPharmaceuticals, Inc.: 2/2021.
- 10. Bylvay [™] [package insert]. Boston, MA: Albireo Pharma, Inc.: 7/2021.
- 11. Livmarli ™ [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.: 10/2021.
- 12. Tarpeyo ™ [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB.: 12/2021.
- 13. Tavneos ™ [package insert]. San Carlos, CA: ChemoCentryx, Inc.: 10/2021.
- 14. Voxzogo ™ [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.: 12/2021.
- 15. Recorlev [®] [package insert]. Chicago, IL: Xeris Pharmaceuticals, Inc.: 1/2022.
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