denotes change in current criteria
denotes new criteria

Xywav

Xyrem is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy

Xywav is a central nervous system depressant indicated for the treatment of: (1) Cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy (2) Idiopathic Hypersomnia (IH) in adults

Prior authorization requests for Xyrem/Xywav will be approved if the following criteria are met:

1) Diagnosis of narcolepsy with excessive daytime sleepiness (EDS) and/or cataplexy as confirmed by a sleep study followed by multiple sleep latency testing (MSLT) or Diagnosis of idiopathic Hypersomnia (for Xywav); **AND**

2) The medication is prescribed by a sleep specialist enrolled in the Xywav and Xyrem® REMS Program; **AND**

3) The member is enrolled in Xywav and Xyrem REMS Program; **AND**

4) The member does not have a history or succinic semialdehyde dehydrogenase deficiency; **AND**

5) The member is not receiving concurrent treatment with sedative hypnotics or central nervous system depressants; **AND**

6) The member has a recent drug screen negative for benzodiazepines, opiates, and illicit drugs; **AND**

7) The member has a documented history of alcohol abstinence; **AND**

8) Member does not have a history of substance abuse; **AND**

9) Member does not have a condition which would require a restricted intake of sodium such as, but not limited to, hypertension or stage 4-5 renal impairment.

For narcolepsy with daytime sleepiness, must have documented history of therapeutic failure of the following, as determined by an Epworth Sleepiness scale of greater than or equal to 10 or repeated maintenance of Wakefulness Test (MWT) or MSLT with a mean sleep latency of 8 minutes or less;

1) Modafinil or Armodafinil at maximum recommended doses; **AND**

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denotes new criteria

2) Methylphenidate, methamphetamine or dextroamphetamine at maximum recommended doses; **OR**
3) Intolerance to or contraindication for the above agents

For narcolepsy with cataplexy, must have documented history of therapeutic failure, contraindication, or intolerance to:

1) Tricyclic antidepressants; **AND**
2) SSRIS and SNRIS

For Xywav: Diagnosis of Idiopathic Hypersomnia

1) The member is ≥18 years of age; **AND**
2) Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results; **AND**
3) Must have a 60-day trial of at least one preferred stimulant treatment (e.g., methylphenidate or dextroamphetamine) at maximally tolerated dosage which led to an inadequate treatment response, unless contraindicated; **AND**
4) Must have a 60-day trial of modafinil which resulted in an inadequate treatment response, unless contraindicated.

Xywav will only be approved upon documentation of allergy, intolerance, or contraindication to Xyrem. Requests for Xywav must be accompanied with the 2 most recent basic metabolic panel (BMP) tests.

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BPH TREATMENTS

Current Class Criteria:

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of at least two (2) chemically distinct preferred agents, including the generic formulation of the requested non-preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

Proposed Class Criteria:

CLASS PA CRITERIA: See below for individual sub-class criteria.

5-ALPHA-REDUCTASE (5AR) INHIBITORS AND PDE-5 AGENTS

Non-preferred 5-ALPHA-REDUCTASE (5AR) agents require a thirty (30) day trial of finasteride before they will be approved, unless one (1) of the exceptions on the PA form is present.

Non-preferred PDE-5 agents require thirty (30) day trials of finasteride AND a preferred alpha blocker before they will be approved, unless one (1) of the exceptions on the PA form is present.

ALPHA BLOCKERS

Non-preferred alpha blockers require thirty (30) day trials of at least two (2) preferred agents, including the generic formulation of the requested non-preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

BPH TREATMENTS		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
5-ALPHA-REDUCTASE (5AR) INHIBITORS AND PDE-5 AGENTS		
finasteride	AVODART (dutasteride) CIALIS 5 mg (tadalafil) Dutasteride ENTADFI (finasteride/tadalafil) capsules* PROSCAR (finasteride) tadalafil	Non-preferred 5-ALPHA-REDUCTASE (5AR) agents require a thirty (30) day trial of finasteride before they will be approved, unless one (1) of the exceptions on the PA form is present. Non-preferred PDE-5 agents require thirty (30) day trials of finasteride AND a preferred alpha blocker before they will be approved, unless one (1) of the exceptions on the PA form is present. *Documentation of medical reasoning beyond convnience must be provided as to why the clinical need cannot be met with finasteride used in combination with tadalafil.
ALPHA BLOCKERS		
alfuzosin doxazosin tamsulosin terazosin	CARDURA (doxazosin) CARDURA XL (doxazosin) FLOMAX (tamsulosin) RAPAFLO (silodosin) silodosin	Non-preferred alpha blockers require thirty (30) day trials of at least two (2) preferred agents, including the generic formulation of the requested non-preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

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Camzyos (mavacamten)

CAMZYOS (mavacamten) is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

CRITERIA FOR APPROVAL:

1. Patient must have a documented diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM); **AND**

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

3. The medication is being prescribed by, or in consultation with, a cardiologist; **AND**

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

5. Patient must have left ventricular ejection fraction (LVEF) ≥ 55% AND Valsalva left ventricular outflow track (LVOT) peak gradient ≥50mmHg at rest or with provocation; **AND**

6. The patient has a documented side effect, allergy, or treatment failure at a maximally tolerated dose to at least two of the following, unless contraindicated:

    a. Non-vasodilating beta blocker,
    b. Nondihydropyridine calcium channel blocker,
    c. Disopyramide; **AND**

7. The medication will not be used concurrently with disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker.

Approval Duration: Initial approval will be for 6 months.

Criteria for reauthorization:

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

2. The patient has had a positive clinical response which is supported by one of the following: stable or reduction in New York Heart Association (NYHA) class AND Patient has a left ventricular ejection fraction of greater than or equal to 50%.

Reauthorizations may be approved for 12 months.

denotes change in current criteria
denotes new criteria

Trikafta

TRIKAFTA is a combination of ivacaftor, a CFTR potentiator, tezacaftor, and elexacaftor indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown, an FDA cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data.

CRITERIA FOR APPROVAL:

1. The patient is within the age range as recommended by the FDA label; **AND**

2. Patient must have a confirmed diagnosis of Cystic Fibrosis; **AND**

3. Patient must be determined to have at least one F508del mutation in the CFTR gene as confirmed by an FDA-approved CF mutation test; **AND**

4. Patient must have a documented baseline AST, ALT and for patients 6 years of age and older- FEV1 (forced expiratory volume in one second) presented with the prior authorization request; **AND**

5) Patients under the age of 18 years must have undergone a baseline ophthalmic examination to monitor for lens opacities/cataracts.

Approval Duration: Initial approval will be for 6 months.

Criteria for reauthorization:

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

2. Patients under the age of 18 years must have follow up ophthalmic examinations at least annually (documentation required); **AND**

3. Patient must have LFTs/bilirubin monitored every 6 months for the first year of treatment and annually thereafter (documentation required); **AND**

4. Serum ALT or AST < 5 times the upper limit of normal (ULN); OR 4) Serum ALT or AST < 3 times the ULN with bilirubin < 2 times the ULN.

Reauthorizations may be approved for 12 months.

denotes change in current criteria
denotes new criteria

Leqvio (inclisiran)

LEQVIO (inclisiran) is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

CRITERIA FOR APPROVAL:

1. Patient must meet all age and indication restrictions imposed by the current FDA-approved 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/ezetimibe combination, then they must be trialed on the second combination for 8-weeks or until intolerance occurs; **AND**

3. The patient must have a 90-day trial of each preferred PCSK9 inhibitor (Repatha and Praulent) resulting in treatment failure/inadequate response, unless contraindicated.

Approval Duration: Initial approval will be for 90 days.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; AND

2. Documentation of efficacy supported by at least a 40% LDL-C reduction from pre-treatment level is provided.

Reauthorizations may be approved for 12 months.