



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service
Prior Authorization Criteria

Corlanor[®]
(ivabradine)

[Prior Authorization Request Form](#)

Corlanor is a hyperpolarization-activated cyclic nucleotide-gated (HCN) channel blocker, which affects heart rate. It is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction $\leq 35\%$, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

Criteria for Approval

- 1) Individual is 18 years or older; **AND**
- 2) Individual is using for the treatment of New York Heart Association (NYHA) class II, III, or IV heart failure symptoms; **AND**
- 3) Individual has a left ventricular ejection fraction less than or equal to 35%; **AND**
- 4) Individual will be utilizing in combination with a beta-blocker OR has a contraindication or intolerance to beta-blocker therapy; **AND**
- 5) Individual is in normal sinus rhythm; **AND**
- 6) If initiating treatment with Corlanor, individual has a resting heart rate greater than or equal to 70 beats per minute.

Criteria for Denial

Corlanor (ivabradine) may not be approved for any of the following:

- 1) Individual's heart rate is maintained exclusively by a pacemaker; **OR**
- 2) Individual has severe hypotension (blood pressure less than 90/50)

References

- 1) Corlanor package insert revised 4/2015
- 2) Lexi-Comp Clinical Application 07/17/2015



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Office of Pharmacy Service
Prior Authorization Criteria

Cosentyx[®] (Secukinumab)
[Prior Authorization Request Form](#)

Cosentyx[®] (Secukinumab) is a human IgG1 monoclonal antibody that selectively binds to the interleukin 17-A cytokine and inhibits its interaction with the IL-17 receptor. Cosentyx[®] is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

Prior authorization requests for Cosentyx[®] will be approved if the following criteria are met:

- 1) Must be prescribed by a specialist (i.e a dermatologist); **AND**
- 2) Patient must be eighteen (18) years of age or older and diagnosed with moderate to severe plaque psoriasis; **AND**
- 3) Patient must have documented failure, intolerance or contraindications to NSAIDs; **AND**
- 4) Patient must have failed a sixty (60) day trial of a non-biological disease modifying anti-rheumatic drug (DMARD) such as methotrexate, sulfasalazine, leflunomide, or cyclosporine; **AND**
- 5) Patient must have failed ninety (90) day trials of at least one (1) preferred biological DMARDs.

References

- 1) Cosentyx package insert 1/2015
- 2) Lexi-Comp Clinical Application 9/2/2015



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Prior Authorization Criteria
DAKLINZA[®] (daclatasvir) for Hepatitis C (HCV)

[Prior Authorization Request Form](#)
[Prior Authorization Continuation Request Form](#)
[Patient Consent Form](#)

Daklinza is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir for the treatment of chronic HCV genotype 3 infections.

Criteria for Approval

- 1) Patient must be eighteen (18) years of age or older; **AND**
- 2) Daclatasvir must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
- 3) Patient must be non-cirrhotic and be diagnosed with Hepatitis C Genotype 3; **AND**
- 4) Patient must also have a concurrent prescription for sofosbuvir; **AND**
- 5) Patient must have a documented **fibrosis level \geq F3**. Fibrosis level must be substantiated via biopsy, FibroSure Assay or by Fibroscan; **AND**
- 6) Patient must **not** be co-infected with HIV; **AND**
- 7) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **AND**
- 8) Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**
- 9) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- **Daklinza will only be approvable in combination with Sovaldi as a 12-week regimen for the treatment of non-cirrhotic GT-3 HCV infection.**
- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level.
- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**



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Criteria for Denial

- 1) Patient has HIV co-infection.
- 2) Diagnosis for any genotype other than GT 3.
- 3) Patient is awaiting liver transplant.
- 4) Patient is post-liver transplant (safety and efficacy have not been established).
- 5) Patient is not sofosbuvir naïve.
- 6) Prescriber has determined that the patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment.
- 7) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis.
- 8) Patient is taking a concomitant medication that has a significant clinical interaction with sofosbuvir:
 - a. tipranavir/ritonavir
 - b. rifampin, rifabutin, rifapentine
 - c. carbamazepine, phenytoin, phenobarbital, oxcarbazepine
 - d. St. John's wort
- 9) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

- 1) Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.
- 2) Daclatasvir is an inhibitor of the hepatitis C virus NS5A protein.
- 3) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.
- 4) Lost or stolen medication replacement request will not be authorized.

References

- 1) FDA News Release. FDA approves new treatment for chronic hepatitis C genotype 3 infections. July 24, 2015.
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455888.htm>
- 2) Daklinza [package insert]. Bristol-Myers Squibb Company, July 2015.
- 3) Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.



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Office of Pharmacy Service
Prior Authorization Criteria

EVZIO® (naloxone auto-injection)
[Prior Authorization Request Form](#)

Evzio is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present. Evzio is not a substitute for emergency medical care.

It is strongly recommended that the prescriber complete the Opioid Overdose Risk Assessment Checklist Form and submit for documentation. The link below is for the form: <http://evzio.com/pdfs/Evzio-Opioid-Overdose-Risk-Assessment-Checklist.pdf>

Evzio will be authorized for one (1) year at a quantity limit of four (4) per claim (two (2) boxes - 1.6 ml) if the following criteria have been met:

- 1.) Patient must be receiving addiction counseling services if the diagnosis is substance abuse, dependence and/or addiction; such as psychosocial therapy from a Substance Abuse provider. Documentation provided must include provider name, type of provider, and provider phone number.

AND

- 2.) The medication is to be administered outside of a healthcare facility (such as a personal residence or school)

AND

- 3.) Request must document why naloxone syringes cannot be used. Claims history must indicate at least two (2) previous fills of the naloxone syringes as evidence that an effort has been made to use that product.

References

- 1) Lexi-Comp drug monograph for Evzio (Nov. 10th, 2014)
- 2) www.Evzio.com
- 3) Evzio package insert (rev 4/2014)



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Office of Pharmacy Service
Prior Authorization Criteria

HUMIRA® (adalimumab) and ENBREL® (etanercept)
Prior Authorization Request Form

Prior authorization requests for Humira and Enbrel will be approved for the listed indications if the following criteria are met. Diagnoses must accompany all requests.

1. **Humira** is eligible for coverage for the following indications:

- a. Ankylosing spondylitis
- b. Psoriasis
- c. Psoriatic arthritis
- d. Rheumatoid arthritis
- e. Juvenile idiopathic arthritis
- f. Crohn's Disease
- g. Pediatric Crohn's Disease
- h. Ulcerative Colitis
- i. Hidradenitis Suppurativa (HS)

2. **Enbrel** is eligible for coverage for the following indications:

- a. Ankylosing spondylitis
- b. Psoriasis
- c. Psoriatic arthritis
- d. Rheumatoid arthritis
- e. Juvenile idiopathic arthritis

1. Patient must be eighteen (18) years of age or older unless diagnosed with juvenile idiopathic arthritis or pediatric Crohn's disease; **AND**
2. Initial treatment plan must be done in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist); **AND**
3. Negative tuberculin skin test before initiation of therapy;

AND the following indication-Specific Prior Authorization Criteria

1. **Ankylosing spondylitis**: must include documentation indicating ninety (90) day treatment history with NSAIDs (unless contraindicated).
2. **Psoriasis** must have:
 - i. Diagnosis of moderate to severe psoriasis (equal to or less than 10% of the body affected); **AND**
 - ii. Prior treatment with a potent topical corticosteroid plus calcipotriol; **AND**
 - iii. Prior treatment with a Vitamin D analogue; **AND**
 - iv. Prior treatment with phototherapy; **AND**
 - v. Prior ninety (90) day treatment history with a disease-modifying agent (DMARD) such as methotrexate, cyclosporine, acitretin, etc.



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3. **Psoriatic arthritis or rheumatoid arthritis:** must have a documented ninety (90) day history of NSAID therapy as well as ninety (90) day trials of at least two DMARDs.
4. **Juvenile idiopathic arthritis:** Prior authorization may be granted for ***Humira*** if the patient is four (4) years of age or older; ***Enbrel*** may be granted a PA if the patient is two (2) years of age or older. In either case, the patient must have tried and failed a ninety (90) day course of therapy with methotrexate.
5. **Crohn's Disease:** ***Humira*** is approvable for moderate to severe Crohn's disease. ***Enbrel*** is not indicated for treatment of Crohn's disease and will not be approved.
6. **Pediatric Crohn's disease:** (moderate to severe) – For patients 6 years of age and older, prior authorization requests for ***Humira*** are approvable with documentation of an inadequate response to a 14-day trial of corticosteroids or an immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate.
7. **Ulcerative Colitis:** ***Humira*** is approvable following failure or clinically significant adverse effects to a thirty (30) day course of aminosalicylates (e.g. sulfasalazine, mesalamine) requiring treatment for two (2) or more exacerbations using corticosteroids, such as prednisone. ***Enbrel*** is not indicated for treatment of UC and will not be approved.
8. **Hidradenitis Suppurativa (HS):** ***Humira*** is approvable for the treatment of moderate to severe HS. Requests must be accompanied with a documented diagnosis of HS and should be prescribed by, or in consultation with a dermatologist.

References

- 4) Lexi-Comp drug monographs for Humira and Enbrel (Nov. 4th, 2014)
- 5) Humira Package Insert (9/2015)
- 6) Enbrel Package Insert
- 7) Francisco A. Kerdel, BSc, MBBS June 2014 Skin and Allergy News Hidradenitis Suppurativa: Update on Diagnosis and Treatment; Current and Emerging Nonsurgical Treatment Options for Hidradenitis Suppurativa
- 8) Options for Hidradenitis Suppurativa
- 9) J Braun *et al.* 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
- 10) Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults. A national clinical guideline. Edinburgh (Scotland); Scottish Intercollegiate (SIGN), 2010 Oct (SIGN publication, no. 121 (217 references)
- 11) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009



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Office of Pharmacy Service
Prior Authorization Criteria

INVEGA TRINZA™
(paliperidone palmitate)
[Prior Authorization Request Form](#)

Invega Trinza™, a 3-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna® (1-month paliperidone palmitate extended-release injectable suspension) for at least four months.

Prior authorization requests for Invega Trinza™ will be approved if the following criteria are met:

- a. Patient must be eighteen (18) years of age or older; **AND**
- b. Patient must have a diagnosis of schizophrenia; **AND**
- c. Invega Trinza is to be used only after Invega Sustenna (1-month paliperidone palmitate extended-release injectable suspension) has been established as adequate treatment for at least four months; **AND**
- d. The last two doses of Invega Sustenna should be the same dosage strength before starting Invega Trinza.

References

- 1) Invega Trinza™ package insert 5/2015
- 2) Lexi-Comp Clinical Application 9/21/2015



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Office of Pharmacy Service
Prior Authorization Criteria

MYALEPT® (metreleptin)
[Prior Authorization Request Form](#)

Myalept® is a leptin analog indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

Criteria for Approval

- 1) Myalept will ONLY be authorized for FDA-approved indications; **AND**
- 2) Patient must be diagnosed with a leptin deficiency (documentation must be provided); **AND**
- 3) Patient must be diagnosed with congenital or acquired generalized lipodystrophy; **AND**
- 4) Members with diabetes mellitus or insulin resistance must have tried and failed two previous antidiabetic therapies; **AND**
- 5) Members with hypertriglyceridemia must have tried and failed therapy with a fibrate (with or without a statin) or be unable to take fibrates and must be receiving a low-carbohydrate diet.

Criteria for Denial

- 1) Prior authorization will be denied for patients with a metabolic disease (e.g diabetes mellitus, hypertriglyceridemia, insulin resistance) in the absence of a concurrent diagnosis of congenital or acquired generalized lipodystrophy; **OR**
- 2) Diagnosis of HIV-related lipodystrophy; **OR**
- 3) Evidence of liver-disease; **OR**
- 4) Presence of anti-metroleptin antibodies

Criteria for Continuation of Coverage

- 1) Claims history must indicate reasonable compliance; **AND**
- 2) Patient responding to treatment (documentation is required); **AND**
- 3) Patient tolerating treatment; **AND**
- 4) Patient does not have anti-metroleptin antibodies; **AND**
- 1) Patient has a clinically significant improvement in HbA1c, triglyceride levels, and/or fasting glucose levels.

References

- 12) Myalept package insert revised 8/2015
- 13) Lexi-Comp Clinical Application 09/18/2015



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Office of Pharmacy Service
Prior Authorization Criteria

ORKAMBI®
(lumacaftor/ivacaftor)
[Prior Authorization Request Form](#)

Orkambi is a combination drug containing lumacaftor and ivacaftor that is indicated for the treatment of cystic fibrosis in patients 12 years of age and older who are **homozygous** for the **F508del** mutation in the CFTR gene.

Criteria for Approval

- 1) Individual is 12 years or older; **AND**
- 2) Patient must have a confirmed diagnosis of Cystic Fibrosis; **AND**
- 3) Patient must be determined to be **homozygous** for the **F508del** mutation in the CFTR gene as confirmed by an FDA-approved CF mutation test; **AND**
- 4) Patient must have a documented baseline FEV₁ (forced expiratory volume in one second) presented with the prior authorization request; **AND**
- 5) If the patient is between the ages of 12-18, they must have undergone a baseline ophthalmic examination to monitor for lens opacities/cataracts.

Prior authorizations will be for every 3 months in the first year, followed thereafter by an annual prior authorization.

Criteria for Continuation of Therapy

- 1) Pediatric patients between the ages of 12 and 18 must have follow up ophthalmic examinations at least annually (documentation required)
- 2) Patient must have stable or improved FEV₁; **AND**
- 3) Clinical notes must also be supplied that document stable or improved patient symptoms; **AND**
- 4) Patient must have LFTs/bilirubin monitored every 3 months for the first year of treatment and annually thereafter; **AND**
- 5) Serum ALT or AST < 5 times the upper limit of normal (ULN); **OR**
- 6) Serum ALT or AST < 3 times the ULN with bilirubin < 2 times the ULN.

References

- 14) Orkambi package insert revised 7/2015
- 15) Lexi-Comp Clinical Application 09/17/2015



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Office of Pharmacy Service
Prior Authorization Criteria

PRALUENT[®]
(alirocumab)

[Prior Authorization Request Form](#)

Praluent[®] is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C).

Criteria for Approval

- 1) Individual is 18 years or older; **AND**
- 2) Must be prescribed by or in consultation with a cardiologist or lipid specialist; **AND**
- 3) Presence of causal mutation for familial hypercholesterolemia by genetic testing; **OR** Definitive clinical evidence supporting the diagnosis of familial hypercholesterolemia (documentation must be provided); **OR**
- 4) The patient has a documented diagnosis of ASCVD, defined as one of the following: acute coronary syndrome, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin; **AND**
- 5) Documentation indicating that treatment with at least two 12-week trials of different high-intensity statins used concomitantly with ezetimibe (Zetia) has been ineffective. Adherence to the current statin regimen must be evidenced by consistent pharmacy claims; **AND**
- 6) The patient will be using Praluent concomitantly with a maximally-tolerated statin

Criteria for Continuation

- 1) Hypercholesterolemia, ASCVD: Documentation that LDL-C < 100 mg/dL or there has been at least a 40% LDL-C reduction from pre-treatment level; **AND**
- 2) Documentation that the member has been adherent to treatment with statin and PCSK9 inhibitor as demonstrated by consistent pharmacy claims.

References

- 1) Praluent package insert revised 7/2015
- 2) Lexi-Comp Clinical Application 09/18/2015



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- 3) Stone, N. J., Robinson, J., Lichtenstein, A. H., et al. 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Retrieved from: <http://circ.ahajournals.org>.
- 4) 2. Goldberg, A. C., Hopkins, P. N., Toth, P. P., et al. Familial hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J. of Clinical Lipidology* 2011 Volume 5, Number 3S.



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Office of Pharmacy Service
Prior Authorization Criteria

RELISTOR[®] (methylnaltrexone) Injection
[Prior Authorization Request Form](#)

Relistor[®] is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain and for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.

Prior authorization requests for Relistor will be approved if the following criteria are met:

- 1) Patient is receiving **palliative care** and has **opioid induced constipation;**
AND
- 2) Documented failure of therapy with stimulant, osmotic and bulk forming laxatives;

OR

- 1) Patient has **opioid-induced constipation with chronic non-cancer pain;**
AND
- 2) Documented failure of therapy with stimulant, and osmotic laxatives; **AND**
- 3) Documented failure of 30 day trials of both Amitiza and Linzess.

NOTE: The maximum approvable duration of therapy is four (4) months.

References

- 16) Relistor package insert revised 9/2014
- 17) Lexi-Comp Clinical Application 09/18/2015



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Prior Authorization Criteria
TECHNIVIE® (ombitasvir/parataprevir/ritonavir) for Hepatitis C (HCV)

[Prior Authorization Request Form](#)
[Prior Authorization Continuation Request Form](#)
[Patient Consent Form](#)

Technivie® is a fixed-dose combination of ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis.

Criteria for Approval

- 1) Patient must be eighteen (18) years of age or older; **AND**
- 2) Technivie® must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
- 3) Patient must be non-cirrhotic and be diagnosed with Hepatitis C Genotype 4; **AND**
- 4) Patient must have a documented **fibrosis level \geq F3**. Fibrosis level must be substantiated via biopsy, FibroSure Assay or by Fibroscan; **AND**
- 5) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **AND**
- 6) Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**
- 7) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- **Technivie will only be approvable in combination with ribavirin as a 12-week regimen for the treatment of non-cirrhotic GT - 4 HCV infections.**
- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level
- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**



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Criteria for Denial

- 1) Diagnosis for any genotype other than GT 4.
- 2) Prescriber has determined that the patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment.
- 3) Patient is on dialysis.
- 4) Patient is taking a concomitant medication that has a significant clinical interaction with Technivie[®] (refer to package insert for a listing of interacting medications).
- 5) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

- 1) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.
- 2) Lost or stolen medication replacement request will not be authorized.

References

- 1) Lexi-Comp Clinical Application 09/21/2015
- 2) Technivie[®] [package insert]. Abbvie, Revised 7/2015
- 3) AASLD 2015 Recommendations for Testing, Managing and Treating Hepatitis C (<http://www.hcvguidelines.org>)



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Office of Pharmacy Service
Prior Authorization Criteria

XIFAXIN® (rifaximin)
Prior Authorization Request Form

Xifaxin® (rifaximin) is a rifamycin antibacterial indicated for:

- I) Treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older.
- II) Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.
- III) Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

Indication –specific Criteria for Approval

- I) **Traveler's diarrhea** (caused by non-invasive strains of *Escherichia coli*)
 1. Request must be for Xifaxan 200 mg tablets; **AND**
 2. Patient must be between twelve (12) and eighteen (18) years of age; **OR**
 3. Patients over eighteen (18) years of age must have had a previous trial of ciprofloxacin.

- II) **Hepatic encephalopathy**
 1. Request must be for Xifaxin 550 mg tablets; **AND**
 2. Patient must be eighteen (18) years of age or older; **AND**
 3. History of treatment with lactulose. *If lactulose has been discontinued, documentation must be included indicating lack of efficacy or the occurrence of an adverse effect.*

- III) **Irritable bowel syndrome with diarrhea (IBS-D)**
 - 1) Request must be for Xifaxin 550 mg tablets; **AND**
 - 2) Patient must be eighteen (18) years of age or older; **AND**
 - 3) History of a trial of metronidazole or neomycin (unless contraindicated); **AND**
 - 4) History of failure, contraindication or intolerance to **one** of the following:
 - a. Antispasmodic (for example: dicyclomine, hyoscyamine)
 - b. Tricyclic antidepressant (for example: amitriptyline)

All other requests will be approved on a case-by-case basis.



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References

- 1) Lexi-Comp Clinical Application 09/21/2015
- 2) Xifaxin package insert (Rev 5-2015)
- 1) American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. *Am J Gastroenterol* 2014; 109:S2 – S26; doi: 10.1038/ajg.2014.187. (http://gi.org/wp-content/uploads/2014/08/IBS_CIC_Monograph_AJG_Aug_2014.pdf)
- 2) *Am Fam Physician*. 2009 Jun 15;79(12):1108-1117.
<http://www.aafp.org/afp/2009/0615/p1108.html>
- 3) http://www.cdc.gov/Ncidod/dbmd/diseaseinfo/travelersdiarrhea_g.htm
- 4) http://www.aasld.org/sites/default/files/guideline_documents/hepaticencephenhanced.pdf
- 5) <http://pharmpractice.ku.edu/journal-club-digest/rifaximin-use-treatment-hepatic-encephalopathy>
- 6) Rifaximin treatment in hepatic encephalopathy. *N Engl J Med*. 2010 Mar 25;362(12):1071-81