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Subject: Ozanimod (Zeposia®) Capsules

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Multiple sclerosis (MS) is a chronic disease affecting the central nervous system (CNS). It is characterized by triad of inflammation, demyelination, and scarring of the central nervous system and manifests as pathological (immune-mediated CNS demyelination and axonal injury) and clinical (exacerbations, disability progression) dissemination in time and space. Although the clinical course of the disease is capricious, MS has been categorized into four types: clinically isolated syndrome (CIS), relapsing-remitting (RRMS), secondary progressive (SPMS), and primary progressive (PPMS). The most common type is RRMS, which is characterized by acute attacks followed by periods of remission. An initial attack may present as a clinically isolated syndrome (CIS); individuals presenting with this syndrome are high risk for subsequent conversion to clinically definite MS (CDMS) when coupled with MRI lesions consistent with MS. Although a cure for MS remains elusive, several treatment options slow the progression of the disease and reduce the frequency of relapses.

Ozanimod (Zeposia®) is an immunomodulatory agent that is used to reduce the frequency of relapses and delay the accumulation of physical disability in patients with RRMS. Ozanimod exerts its physiologic effects through attachment to the sphingosine-1 phosphate receptor, which is plays a role in immune function regulation. Ozanimod is Food and Drug administration (FDA) approved for the treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Ozanimod is also FDA approved in adults for the treatment of moderately to severely active ulcerative colitis.

The efficacy of ozanimod was compared to interferon-beta-1a in two randomized, controlled trials over a 1 or 2 year time period. Patients with relapsing forms of multiple sclerosis who had experienced at least 1 relapse within the prior year, or 1 relapse within the prior 2 years with evidence of at least a gadolinium-enhancing (GdE) lesion in the prior year, and had an Expanded Disability Status Scale (EDSS) score from 0 to 5 at baseline were included. In both trials, ozanimod significantly improved the primary

endpoint of annualized relapse rate (ARR) as compared to interferon beta-1a (0.181 vs 0.35 for trial 1, 0.172 vs 0.276 for trial 2; p<0.0001). Additionally, ozanimod significantly reduced the mean number of new or enlarging T2 brain MRI lesions (1.47 vs 2.84 for trial 1, 1.84 vs 3.18 for trial 2; p<0.0001) and T1 GdE lesions compared to interferon beta-1a (0.16 vs 0.43 for trial 1, 0.18 vs 0.37 for trial 2; p-value <0.001). There was no significant difference between groups in confirmed disability progression at 3 months (7.6% vs 7.8%). The most common adverse reactions that occurred with ozanimod use were upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, and back pain.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

NOTE: Avonex, Betaseron, Kesimpta, Mavenclad, Mayzent, Plegridy, Rebif, and Zeposia are the preferred brand products for treatment of relapsing forms of multiple sclerosis. The preferred generic products include dimethyl fumarate (generic), fingolimod (generic), glatiramer acetate (generic by Mylan), and teriflunomide(generic). Dimethyl fumarate (generic), fingolimod (generic), glatiramer acetate (generic by Mylan, Glatopa), and teriflunomide (generic) do not require prior authorization.

Initiation of ozanimod (Zeposia®) **meets the definition of medical necessity** for **EITHER** of the following indications when **ALL** of the indication-specific criteria are met:

A. Multiple sclerosis
   1. The member is diagnosed with **ONE** of the following forms of multiple sclerosis (MS):
      a. Relapsing remitting multiple sclerosis [RRMS]
      b. Active secondary progressive MS [SPMS]
      c. First clinical episode and member has MRI features consistent with MS
   2. **ONE** of the following (a, b, or c):
      a. The patient has highly active MS disease activity and **BOTH** of the following:
         i. The patient has ≥ 2 relapses in the previous year
         ii. **ONE** of the following:
            1. The patient has ≥ 1 gadolinium enhancing lesion on MRI
            2. The patient has significant increase in T2 lesion load compared with a previous MRI
      b. The patient has been treated with at least 3 MS agents from different drug classes

c. **ONE** of the following (i, ii, iii, or iv):

i. The patient has tried and had an inadequate response to dimethyl fumarate (generic), fingolimod (generic), glatiramer acetate (generic by Mylan, Glatopa), **OR** teriflunomide (generic)

ii. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to dimethyl fumarate (generic), fingolimod (generic), glatiramer acetate (generic by Mylan, Glatopa), **OR** teriflunomide (generic)

iii. The patient has a FDA labeled contraindication to dimethyl fumarate (generic), fingolimod (generic), glatiramer acetate (generic by Mylan, Glatopa), **AND** teriflunomide (generic)

iv. The prescriber has provided information in support of using the requested agent over dimethyl fumarate (generic), fingolimod (generic), glatiramer acetate (generic by Mylan, Glatopa), **AND** teriflunomide (generic)

3. Ozanimod will not be used in combination with an additional disease modifying agent (DMA) (full list in "Other" section)

4. The member does not have **ANY** of the following FDA labeled contraindications:

a. History (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or NYHA Class III/IV heart failure

b. History or presence of Mobitz Type II second- or third-degree AV block , sick sinus syndrome, or sino-atrial block (unless member has a functioning pacemaker)

c. Severe untreated sleep apnea

d. Concomitant use of a monoamine oxidase inhibitor (e.g., selegiline, phenelzine, linezolid)

5. The dosage does not exceed 0.92 mg daily

B. Ulcerative colitis

1. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) **AND ALL** of the following ("a", "b",and "c"):

a. **ONE** of the following:

i. The patient has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC for at least 3-months

ii. The patient has severely active ulcerative colitis

iii. The patient has an intolerance or hypersensitivity to **ONE** of the conventional agents used in the treatment of UC

iv. The patient has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of UC

v. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a for the treatment of UC

b. **ONE** of the following (submitted medical records/chart notes are required for confirmation):

i. The patient has tried and had an inadequate response to at least **TWO** of the following for at least 3 months:

- Amjevita (adalimumab-atto) low-concentration product [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only]
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)
- Rinvoq (upadacitinib)
- Stelara (ustekinumab)
- Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended release)

ii. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **TWO** of the following:

- Amjevita (adalimumab-atto) low-concentration product [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only]
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)
- Rinvoq (upadacitinib)
- Stelara (ustekinumab)
- Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended release)

iii. The patient has an FDA labeled contraindication to **ALL** of the following:

- Amjevita (adalimumab-atto) low-concentration product [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only]
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)
- Rinvoq (upadacitinib)
- Stelara (ustekinumab)
- Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended release)

iv. The prescriber has provided information indicating why **ALL** of the following are not clinically appropriate for the patient, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication:

- Amjevita (adalimumab-atto) low-concentration product [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only]
- Hadlima (adalimumab-bwwd)
- Humira (adalimumab)

- Rinvoq (upadacitinib)
- Stelara (ustekinumab)
- Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended release)

c. The prescriber has performed an electrocardiogram within 6 months prior to initiating treatment

2. **ONE** of the following:
    a. The patient's age is within FDA labeling for the requested indication for the requested agent
    b. The prescriber has provided information in support of using the requested agent for the patient's age
3. Ozanimod will not be used in combination with **ANY** of the following:
    a. An additional disease modifying agent (DMA) (full list in "Other" section)
    b. A biologic immunomodulatory agent (full list in "Other" section)
    c. Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]
    d. Otezla (apremilast)
    e. Sotyktu (deucravacitinib)
    f. Sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod)]
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g.,gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis
5. The member does not have **ANY** of the following FDA labeled contraindications:
    a. History (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or NYHA Class III/IV heart failure
    b. History or presence of Mobitz Type II second- or third-degree AV block , sick sinus syndrome, or sino-atrial block (unless member has a functioning pacemaker)
    c. Severe untreated sleep apnea
    d. Concomitant use of a monoamine oxidase inhibitor (e.g., selegiline, phenelzine, linezolid)
6. The dosage does not exceed 0.92 mg daily

Approval duration: 1 year

Continuation of ozanimod therapy **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Member has demonstrated a beneficial response to therapy for treatment of RRMS, active SPMS, clinically isolated syndrome, or ulcerative colitis

2. Authorization/reauthorization for ozanimod has been previously approved by Florida Blue or another health plan in the past 2 years, **OR** the member currently meets all indication-specific initiation criteria
3. When used for the treatment of ulcerative colitis, the prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis
4. The member does not have **ANY** of the following FDA labeled contraindications:
    a. History (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or NYHA Class III/IV heart failure
    b. History or presence of Mobitz Type II second- or third-degree AV block, sick sinus syndrome, or sino-atrial block (unless member has a functioning pacemaker)
    c. Severe untreated sleep apnea
    d. Concomitant use of a monoamine oxidase inhibitor (e.g., selegiline, phenelzine, linezolid)
5. Ozanimod will not be in combination with **ANY** of the following:
    a. An additional disease modifying agent (DMA) (full list in "Other" section)
    b. A biologic immunomodulator (full list in "Other" section)
    c. Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]
    d. Otezla (apremilast)
    e. Sotyktu (deucravacitinib)
    f. Sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod)]
6. The dose does not exceed 0.92 mg daily

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Moderately to severely active ulcerative colitis (UC) in adults.
- The recommended maintenance dosage after the initial titration is 0.92 mg taken orally once daily started on Day 8. Capsules should be swallowed whole and can be taken with or without food.

- Initiate treatment according to the following titration:

Days 1-4	0.23 mg once daily
Days 5-7	0.46 mg once daily
Days 8 and thereafter	0.92 mg once daily

- If a dose is missed during the first 2 weeks of treatment, reinitiate using the initial titration. If a dose is missed after the first 2 weeks of treatment, continue with the treatment as planned.
- Prior to treatment, assess the following:
    - Complete blood count (CBC)
    - Cardiac evaluation including an electrocardiogram (ECG)
    - Transaminase and bilirubin levels
    - Ophthalmic assessment in patients with a history of uveitis or macular edema
    - Current or prior medications for additive immunosuppressive effects, heart rate effects, atrioventricular conduction effects, or drug interactions.
    - Test for antibodies to varicella zoster virus and vaccinate if antibody-negative prior to treatment (if live attenuated vaccine is required, it should be administered at least 1 month prior to imitation)

Dose Adjustments

- See dose titration during initiation of therapy

Drug Availability

- 0.23, 0.46, and 0.92 mg capsules

PRECAUTIONS:

Boxed Warning

- none

Contraindications

- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure
- Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
- Severe untreated sleep apnea
- Concomitant use of a monoamine oxidase inhibitor

Precautions/Warnings

- Bradyarrhythmia and Atrioventricular Conduction Delays: may result in transient decrease in heart rate; titration is required for treatment initiation. Check an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate
- Fetal Risk: Women of childbearing potential should use effective contraception during treatment and for 3 months after stopping
- Increased Blood Pressure (BP): Monitor BP during treatment
- Infections: may increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 3 months after discontinuation. Do not start in patients with active infections
- Liver Injury: Discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating
- Macular Edema: A prompt ophthalmic evaluation is recommended if there is any change in vision while taking. Diabetes mellitus and uveitis increase the risk of macular edema; patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation
- Posterior reversible encephalopathy syndrome (PRES) have been reported in patients receiving a S1P receptor modulator. In controlled clinical trials, one case of PRES was reported with treatment.
- Respiratory Effects: May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated
- Unintended additive immunosuppressive effects: When switching from drugs with prolonged immune effects, the half-life and mode of action of these drugs must be considered to avoid unintended additive immunosuppressive effects while at the same time minimizing risk of disease reactivation, when initiating treatment
- Progressive multifocal leukoencephalopathy (PML): withhold at the first sign or symptom suggestive of PML. Immune reconstitution inflammatory syndrome (IRIS) has been reported in patients treated with fingolimod who developed PML and subsequently discontinued treatment. IRIS presents as a clinical decline in the patient's condition that may be rapid, can lead to serious neurological complications or death, and is often associated with characteristic changes on MRI. Monitor for development of IRIS.
- Vaccination: Avoid use of live attenuated vaccines during and for up to 3 months after treatment.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J8499	Prescription drug, oral, nonchemotherapeutic, NOS

ICD-10 Diagnosis Codes That Support Medical Necessity

G35	Multiple sclerosis

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Clinically isolated syndrome (CIS): the first clinical presentation of disease that shows characteristics of inflammatory demyelination that could be MS but has yet to fulfill criteria of dissemination in time.

Primary-progressive multiple sclerosis (PPMS): Steadily progressive course from onset; occurs in 10-15% of patients with MS.

Relapsing-remitting multiple sclerosis (RRMS): Characterized by acute attacks followed by periods of remission; primary form of MS that occurs in approximately 85% of patients.

Secondary-progressive multiple sclerosis (SPMS): An initial period of RRMS, followed by a steadily progressive course, with acute relapses (active disease) or without acute relapses (not active disease); 75-85% of patients diagnosed with RRMS will transition to SPMS.

RELATED GUIDELINES:

Abatacept (Orencia), 09-J0000-67
Adalimumab (Humira), 09-J0000-46
Alemtuzumab (Lemtrada), 09-J2000-27
Anakinra (Kineret), 09-J0000-45
Apremilast (Otezla) Tablet, 09-J2000-19
Baricitinib (Olumiant), 09-J3000-10
Brodalumab (Siliq) Injection, 09-J2000-74
Canakinumab (Ilaris) Injection, 09-J1000-14
Certolizumab Pegol (Cimzia), 09-J0000-77
Cladribine (Mavenclad), 09-J3000-34
Dimethyl Fumarate (Tecfidera), Diroximel fumarate (Vumerity), Monomethyl fumarate (Bafiertam), 09-J1000-96
Etanercept (Enbrel), 09-J0000-38
Fingolimod (Gilenya), 09-J1000-30
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Guselkumab (Tremfya), 09-J2000-87

Ixekizumab (Taltz), 09-J2000-62
Multiple Sclerosis Self Injectable Therapy, 09-J1000-39
Natalizumab (Tysabri) Injection, 09-J0000-73
Ocrelizumab (Ocrevus), 09-J2000-78
Ofatumumab (Kesimpta), 09-J3000-84
Risankizumab (Skyrizi), 09-J3000-45
Rituximab (Rituxan), 09-J0000-59
Sarilumab (Kevzara), 09-J2000-87
Secukinumab (Cosentyx), 09-J2000-30
Siponimod (Mayzent), 09-J3000-35
Teriflunomide (Aubagio), 09-J1000-82
Tildrakizumab-asmn (Ilumya), 09-J3000-04
Tocilizumab (Actemra) Injection, 09-J1000-21
Tofacitinib (Xeljanz, Xeljanz XR) Tablets, 09-J1000-86
Ustekinumab (Stelara), 09-J1000-16
Vedolizumab (Entyvio) Injection, 09-J2000-18

OTHER:

Disease Modifying Agents Not Permitted as Concomitant Therapy

Aubagio (teriflunomide)
Avonex (interferon beta-1a)
Bafiertam (monomethyl fumarate)
Betaseron (interferon beta-1b)
Briumvi (ublituximab)
Copaxone (glatiramer)
Extavia (interferon beta-1b)
Gilenya (fingolimod)
Glatopa (glatiramer)
Kesimpta (ofatumumab)
Lemtrada (alemtuzumab)
Mavenclad (cladribine)
Mayzent (siponimod)
Novantrone (mitoxantrone)
Ocrevus (ocrelizumab)
Plegridy (peginterferon beta-1a)
Ponvory (ponesimod)
Rebif (interferon beta-1a)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumerate)
Truxima (rituximab-abbs)

Tysabri (natalizumab)
Vumerity (diroximel fumarate)

Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy

Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Anakinra (Kineret)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Bimzelx (bimekizumab-bkzx)
Benlysta (belimumab)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Nucala (mepolizumab)
Omvoh (mirikizumab-mrkz)
Orencia (abatacept)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)

Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Wezlana (ustekinumab-auub)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zymfentra (infliximab-dyyb)

REFERENCES:

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3. Comi G, Ludwig K, Selmaj KW et al. Safety and efficacy of ozanimod versus interferon beta-1a in relapsing multiple sclerosis (SUNBEAM): a multicenter, randomized, minimum 12-month, phase 3 trial. Lancet Neurol. 2019; 18 (11): 1009-1020.
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7. National Multiple Sclerosis Society. Accessed 06/03/20.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 10/11/23.

GUIDELINE UPDATE INFORMATION:

07/01/20	New Medical Coverage Guideline.
10/01/20	Revision to guideline; consisting of updating the position statement.

04/01/20	Revision to guideline; consisting of updating the position statement.
06/15/21	Review and revision to guideline; consisting of updating the position statement, description, dosing, related guidelines, and references.
05/15/22	Revision to guideline; consisting of updating the position statement and other section.
10/15/22	Review and revision to guideline; consisting of updating references.
01/01/23	Review and revision to guideline; consisting of updating the position statement to include generic fingolimod as a preferred generic and removal of Gilenya as a preferred brand. Updated list of agents not to be used in combination.
04/15/23	Revision to guideline consisting of updating the position statement and other section.
05/15/23	Revision to guideline; consisting of updating the position statement to include generic teriflunomide as a preferred generic and removal of Aubagio as a preferred brand. Updated list of agents not to be used in combination.
07/01/23	Revision to guideline consisting of updating the position statement and other section. Amjevita and Hadlima added among the step agents for UC. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
11/15/23	Review and revision to guideline; consisting of updating the position statement to include Glatopa and updating references.
01/01/24	Revision to guideline consisting of updating the position statement and other section. Amjevita low-concentration [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only] clarified as the preferred prerequisite product. New drugs were added to the list of drugs that are not permitted for use in combination.