Zeposia Prior Authorization with Quantity Limit

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Zeposia® (ozanimod) Capsule	• Treatment of 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		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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Zeposia PA through preferred	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The patient has a relapsing form of multiple sclerosis (MS) AND BOTH of the following: 1. ONE of the following: A. The patient has highly active MS disease activity AND BOTH of the following: 1. The patient has greater than or equal to 2 relapses in the previous year **AND** 2. ONE of the following: A. The patient has greater than or equal to 1 gadolinium enhancing lesion of MRI **OR** B. The patient has significant increase in T2 lesion load compared with a previous MRI **OR** B. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agent drug class table) **OR** C. ONE of the following: 1. The patient has tried and had an inadequate response to ONE preferred generic MS agent* **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic MS agent* **OR** 3. The patient has an FDA labeled contraindication to ALL preferred generic MS agents* **OR** 4. There is support for using the requested agent over ALL generic MS agents* **AND** 2. ONE of the following: A. The patient will NOT be using the requested agent in combination with another disease modifying agent (DMA)

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	used for the requested indication (Please refer to "MS DMA Agents" contraindicated table) **OR** B. The patient will be using the requested agent in combination with another DMA used for the treatment of MS AND BOTH of the following: 1. The requested agent will be used in combination with Mavenclad (cladribine) **AND** 2. There is support for the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad (cladribine) **OR** B. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following: 1. ONE of the following: A. 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 **OR** B. The patient has severely active ulcerative colitis **OR** C. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** D. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least TWO Step 1a and/orStep1b immunomodulatory agents (see Immunomodulatory Agent Step table) **OR** B. The patient has an intolerance or hypersensitivity to at least TWO Step 1a and/or Step 1b immunomodulatory agents **OR** C. The patient has an FDA labeled contraindication to ALL Step 1a and 1b immunomodulatory agents **AND** 3. ONE of the following (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with an immunomodulatory (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with an immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The prescriber has performed an electrocardiogram within 6 months prior to initiating treatment **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist for the diagnosis of multiple sclerosis, gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

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	4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist for the diagnosis of multiple sclerosis, gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient has a diagnosis of multiple sclerosis AND ONE of the following: 1. The patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) for the requested indication (Please refer to "MS DMA Agents" contraindicated use table **OR** 2. The patient will be using the requested agent in combination with another DMA used for the treatment of the requested indication AND BOTH of the following: A. The requested agent will be used in combination with Mavenclad (cladribine) **AND** B. There is support for the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad) **OR** B. The patient has a diagnosis of ulcerative colitis AND ONE of the following (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table: 1. The patient will NOT be using the requested agent in combination with an immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: A. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND B. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. *** Preferred and Non-preferred MS agents** **Preferred generic agents** dimethyl fumarate fingolimod **Glatopa** (glatiramer)

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glatiramer
teriflunomide

Preferred brand agents
Avonex (interferon b-1a)
Betaseron (interferon b-1b)
Kesimpta (ofatumumab)
Mavenclad (cladribine)
Mayzent (siponimod)***
Plegridy (peginterferon b-1a)
Rebif (interferon b-1a)
Zeposia (ozanimod)

Non-Preferred agents
Aubagio (teriflunomide)**
Bafiertam (monomethyl fumarate)
Copaxone (glatiramer)**
Extavia (interferon b-1b)
Gilenya (fingolimod)**
Ponvory (ponesimod)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumarate)**

** -generic available

*** – Mayzent preferred or non-preferred status is determined by the client

Immunomodulatory Agent Step Table

Preferred adalimumab biosimilar: adalimumab-adbm and adalimumab-fkjp

Step 1a	**Step 2 (Directed to ONE step 1 agent)**	**Step 3a (Directed to TWO Step 1 agents)**	**Step 3b (Directed to TWO agents from step 1a and/or Step 2)**	**Step 3c (Directed to THREE step 1 agents**)
SQ: Preferred adalimumab	SQ inj. Stelara Oral: Xeljanz, Xeljanz XR SQ: Simponi (Preferred adalimumab is required Step 1 agent)	N/A	Oral: Zeposia (Preferred adalimumab Stelara, OR Xeljanz/Xeljanz XR are required step 2 agents) OR Simponi	SQ: Abrilada*, Amjevita* Hadlima*, Hulio*, Hyrimoz*, Idacio*, , Simlandi* Yuflyma*, Yusimry*, Zymfentra *Preferred adalimumab is required Step 1 agents

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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Zeposia PA through preferred	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.