Monjuvi™ (tafasitamab-cxix)

Policy Origination date: November 2020  Number: MG.MM.PH.323

Medical Guideline Disclaimer

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Definition

Monjuvi (tafasitamab-cxix) is an Fc-modified monoclonal antibody that binds to CD19 antigen expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including diffuse large B-cell lymphoma (DLBCL).

Upon binding to CD19, tafasitamab-cxix mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). In studies conducted in vitro in DLBCL tumor cells, tafasitamab-cxix in combination with lenalidomide resulted in increased ADCC activity compared to tafasitamab-cxix or lenalidomide alone.

Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing

Each treatment cycle is 28-days.

Cycle 1:
- 12 mg/kg (actual weight) on Days 1, 4, 8, 15 and 22

Cycle 2 and 3:
- 12 mg/kg (actual weight) on Days 1, 8, 15 and 22
Cycle 4 and beyond:
- 12 mg/kg (actual weight) on Days 1 and 15

Guideline
I. INITIAL APPROVAL CRITERIA
Coverage is provided when the following criteria are met:
- Patient is 18 years of age or older; **AND**
- Monjuvi is prescribed by, or in consultation with, an oncologist; **AND**
- The patient has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified (may include DLBCL arising from low grade lymphoma); **AND**
- The patient has relapsed or refractory disease; **AND**
- The patient is not a candidate for autologous stem cell transplantation (ASCT); **AND**
- Monjuvi will be administered in combination with lenalidomide for a maximum of 12 cycles and will then be continued as monotherapy.

II. RENEWAL APPROVAL CRITERIA
Coverage can be renewed based on the following conditions:
- Stabilization of disease or absence of disease progression; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: infusion-related and hypersensitivity reactions, myelosuppression, infections, etc.; **AND**
- Monjuvi will be used as monotherapy after the initial 12 combination therapy cycles with lenalidomide.

Limitations/Exclusions
n/a

Applicable Procedure Codes

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J9349</td>
<td>Monjuvi, Injection tafasitamab-cxix, 2 mg</td>
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<tr>
<td>C9070</td>
<td>Injection, tafasitamab-cxix; 1 billable unit = 2 mg (Code Deleted 3/31/2021)</td>
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<tr>
<td>J9999</td>
<td>Monjuvi 200 mg solution (Not otherwise classified, antineoplastic drugs)</td>
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Applicable NDCs

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<th>Description</th>
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<tr>
<td>73535-0208-01</td>
<td>Monjuvi (tafasitamab-cxix) 200mg powder single-dose vial</td>
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Applicable Diagnosis Codes

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<tr>
<th>Code</th>
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<tbody>
<tr>
<td>C83.3</td>
<td>Diffuse large B-cell lymphoma</td>
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</table>
Diffuse large B-cell lymphoma, unspecified site
Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
Diffuse large B-cell lymphoma, intrathoracic lymph nodes
Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
Diffuse large B-cell lymphoma, intrapelvic lymph nodes
Diffuse large B-cell lymphoma, spleen
Diffuse large B-cell lymphoma, lymph nodes of multiple sites
Diffuse large B-cell lymphoma, extranodal and solid organ sites

Revision History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Update Description</th>
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<tbody>
<tr>
<td>7/7/2021</td>
<td>Updated billing codes – new J code and expired C Code</td>
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<tr>
<td>1/1/2021</td>
<td>Updated C-code 9070</td>
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<tr>
<td>11/11/2020</td>
<td>New Policy</td>
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References