Tecartus™ (brexucabtagene autoleucel)

Effective Date: January 1, 2021
Number: MG.MM.PH.318

Medical Guideline Disclaimer
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Definition

Brexucabtagene autoleucel is a chimeric antigen receptor (CAR) T-cell gene therapy. It is CD19-directed immunotherapy that works by using a patient’s own genetically altered immune cells to kill B-cell cancer cells in the blood. Brexucabtagene autoleucel is indicated for use in adult patients with mantle cell lymphoma who have not responded to or who have relapsed following other therapy.

Length of Authorization

Coverage will be provided for 14 days (1 dose)

Dosing

Max dose (per dose and over time): $2 \times 10^8$ CAR-positive viable T cells per kg body weight, with a maximum of $2 \times 10^8$ CAR-positive viable T cells

Guideline

Relapsed or refractory mantle cell lymphoma (MCL) †
- Tecartus is prescribed by or in consultation with an oncologist; **AND**
- Patient is 18 years of age and older; **AND**
- Patient has disease that has relapsed or refractory to all other treatment options; **AND**
• Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
• Patient has an ECOG performance status of 0-1; **AND**
• Patient has CD19-positive disease; **AND**
• Patient must not be currently pregnant and sexually-active females of reproductive potential should have pregnancy status verified through a pregnancy test; **AND**
• Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
• Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during Tecartus treatment, and will not receive live vaccines until immune recovery following treatment; **AND**
• Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
• Prophylaxis for infection has been followed according to local guidelines; **AND**
• Patient will be using Tecartus in conjunction with lymphodepleting chemotherapy cyclophosphamide 500 mg/m2 intravenously and fludarabine 30 mg/m2 intravenously on each of the fifth, fourth, and third days before infusion of Tecartus; **AND**
• Healthcare facility has enrolled in the Tecartus REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
• Patient will be using Tecartus at a treatment center that is certified to administer Tecartus; **AND**
• Patient will be monitored for signs and symptoms of Cytokine Release Syndrome (CRS) for at least 7 days after treatment with Tecartus and will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**
• Patient will stay within proximity of the Tecartus infusion center for at least 4 weeks following infusion.

† FDA Approved Indication(s)

### Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C9073</td>
<td>Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose</td>
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### Applicable NDC’s

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>71287-219-xx</td>
<td>Tecartus™ (brexucabtagene autoleucel) 68ml intravenous</td>
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### Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>C83.10</td>
<td>Mantle cell lymphoma</td>
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<tr>
<td>C83.11</td>
<td>Mantle cell lymphoma, lymph nodes of head, face, and neck</td>
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<tr>
<td>C83.13</td>
<td>Mantle cell lymphoma, intra-abdominal lymph nodes</td>
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<tr>
<td>C83.14</td>
<td>Mantle cell lymphoma, lymph nodes of axilla and upper limb</td>
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### C83.15
Mantle cell lymphoma, lymph nodes of inguinal region and

### C83.16
Mantle cell lymphoma, intrapelvic lymph nodes

### C83.17
Mantle cell lymphoma, spleen

### C83.18
Mantle cell lymphoma, lymph nodes of multiple sites

### C83.19
Mantle cell lymphoma, extranodal and solid organ sites

### Revision History

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>1/1/2021</td>
<td>Updated C-code C9073</td>
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<tr>
<td>9/2/2020</td>
<td>New Policy</td>
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### References