MetroPlus Health

Policy and Procedure

Title: Abecma	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 4/26/2022	**LOB: Medicaid, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP**
Effective Date: 4/26/2022	**Policy Number: UM-MP334**
Review Date: 4/25/2023	**Cross Reference Number:**
Retired Date:	**Page 1 of 7**

1. **POLICY DESCRIPTION:**
   Medical Oncology – CAR-T immunotherapy, Abecma (idecabtagene vicleucel)

2. **RESPONSIBLE PARTIES:**
   Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. **DEFINITIONS:**
   Abcema is a chimeric antigen receptor (CAR)-positive T cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T cell activation domain, and a 4-1BB costimulatory domain. Antigen-specific activation of ABECMA results in CAR-positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells.

   Abecma is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

   All other uses for Abecma are considered experimental and investigational.

4. **POLICY:**
   Abecma will be considered medically necessary when the following conditions of coverage have been met:

   Initial Request:
   Multiple myeloma that is refractory or relapsed
   A. Member is 18 years of age or older **AND**
   B. Member has a diagnosis of relapsed or refractory multiple myeloma **AND**
   C. The member has received prior treatment with at least four prior lines of therapy, including at least one drug from each of the following categories:
      a. Immunomodulatory agent [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)]
      b. Proteasome inhibitor [e.g., bortezomib (Velcade), carfilzomib (Kyprolis)]
      c. Anti-CD38 monoclonal antibody [e.g., daratumumab (Darzalex)]
      AND
   D. Member has measurable disease shown by at least one of the following:
      a. Serum monoclonal paraprotein (M-protein) ≥ 1 g/dL

b. Urine M-protein ≥ 200 mg/24 hours
c. Serum immunoglobulin free light chain ≥ 10 mg/dL and abnormal serum free light chain ratio

E. Member has not previously been treated with CAR-T therapy, including Abecma **AND**
F. Member does not have human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection and any autoimmune disease requiring immune suppression **AND**
G. The member does not have an active inflammatory disorder **AND**
H. The medication will be dosed according to FDA guidelines including pretreatment and premedication:
   a. 1 dose- 300 to 460 x 10(6) CAR-positive T cells from 1 or more infusion bags to be given 2 days after completion of lymphodepleting chemotherapy **AND**
I. Healthcare facility/provider has enrolled in the Abecma REMS and has training on the management of cytokine release syndrome (CRS) and neurological toxicities (See Appindices A and B)

Renewal Request:
Repeat administration of Abecma is investigational and will not be covered.

5. LIMITATIONS/ EXCLUSIONS:

All other uses for Abecma are considered experimental and investigational.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
Q2055	Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
Z51.12	Encounter for antineoplastic immunotherapy

8. REFERENCES:

1. Abecma [package insert]. Summit, NJ: Celgene Corporation; March 2021.
2. Munshi NC, Anderson LD, Shah N, et al. Idecabtagene vicleucel in relapsed and refractory multiple myeloma. N Engl J Med. 2021; 348(8): 705-716.
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. [NCCN Web site]. Multiple Myeloma.

9. APPENDIX A: CRS Grading and Management Guidance

<table>
<tr><th>CRS Grade</th><th>Tocilizumab</th><th>Corticosteroids</th></tr>
<tr><td>Grade 1

Symptoms require symptomatic treatment only (e.g., fever, nausea, fatigue, headache, myalgia, malaise).</td><td>If onset 72 hours or more after infusion, treat symptomatically.

If onset less than 72 hours after infusion, consider tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg).</td><td>Consider dexamethasone 10 mg IV every 24 hours.</td></tr>
<tr><td rowspan="2">Grade 2

Symptoms require and respond to moderate intervention.

Oxygen requirement less than 40% FiO2 or hypotension responsive to fluids, or low dose of one vasopressor, or Grade 2 organ toxicity.</td><td>Administer tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg). Repeat tocilizumab every 8 hours as needed if not responsive to intravenous fluids or increasing supplemental oxygen.

Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses</td><td>Consider dexamethasone 10 mg IV every 12-24 hours.</td></tr>
<tr><td colspan="2">If no improvement within 24 hours or rapid progression, repeat tocilizumab and escalate dose and frequency of dexamethasone (20 mg IV every 6 to 12 hours).

If no improvement within 24 hours or continued rapid progression, switch to methylprednisolone 2 mg/kg followed by 2 mg/kg divided 4 times per day.

After 2 doses of tocilizumab, consider alternative anti-cytokine agents. Do not exceed 3 doses of tocilizumab in 24 hours, or 4 doses in total.</td></tr>
</table>

<table>
<tr><td rowspan="2">Grade 3

Symptoms require and respond to aggressive intervention. Fever, oxygen requirement greater than or equal to 40% FiO2, or hypotension requiring high-dose or multiple vasopressors, or Grade 3 organ toxicity</td><td>Administer tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg). Repeat tocilizumab every 8 hours as needed if not responsive to intravenous fluids or increasing supplemental oxygen.

Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses</td><td>Administer dexamethasone 10 mg IV every 12 hours</td></tr>
<tr><td colspan="2">If no improvement within 24 hours or rapid progression, repeat tocilizumab and escalate dose and frequency of dexamethasone (20 mg IV every 6 to 12 hours).

If no improvement within 24 hours or continued rapid progression, switch to methylprednisolone 2 mg/kg followed by 2 mg/kg divided 4 times per day.

After 2 doses of tocilizumab, consider alternative anti-cytokine agents. Do not exceed 3 doses of tocilizumab in 24 hours, or 4 doses in total.</td></tr>
<tr><td rowspan="2">Grade 4

Life-threatening symptoms.

Requirements for ventilator support, continuous veno-venous hemodialysis (CVVHD), or Grade 4 organ toxicity (excluding transaminitis).</td><td>Administer tocilizumab 8 mg/kg IV over 1 hour (not to exceed 800 mg). Repeat tocilizumab every 8 hours as needed if not responsive to intravenous fluids or increasing supplemental oxygen.

Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses</td><td>Administer dexamethasone 20 mg IV every 6 hours</td></tr>
<tr><td colspan="2">After 2 doses of tocilizumab, consider alternative anti-cytokine agents. Do not exceed 3 doses of tocilizumab in 24 hours, or 4 doses in total.

If no improvement within 24 hours, consider methylprednisolone (1-2 g, repeat every 24 hours if needed; taper as clinically indicated) or other anti-T cell therapies.</td></tr>
</table>

10. Appendix B: Neurologic Toxicity Grading and Management Guidance

Neurologic Toxicity Grade	Corticosteroids and Antiseizure Medication
Grade 1	Start non-sedating, antiseizure medicines (e.g., levetiracetam) for seizure prophylaxis. If 72 hours or more after infusion, observe patient. If less than 72 hours after infusion, consider dexamethasone 10 mg IV every 12 to 24 hours for 2 to 3 days
Grade 2	Start non-sedating, antiseizure medicines (e.g., levetiracetam) for seizure prophylaxis. Start dexamethasone 10 mg IV every 12 hours for 2-3 days, or longer for persistent symptoms. Consider taper for a total corticosteroid exposure of greater than 3 days. Corticosteroids are not recommended for isolated Grade 2 headaches. If no improvement after 24 hours or worsening of neurologic toxicity, increase the dose and/or frequency of dexamethasone up to a maximum of 20 mg IV every 6 hours.
Grade 3	Start non-sedating, antiseizure medicines (e.g., levetiracetam) for seizure prophylaxis. Start dexamethasone 10 to 20 mg IV every 6 to 12 hours. Corticosteroids are not recommended for isolated Grade 3 headaches. If no improvement after 24 hours or worsening of neurologic toxicity, escalate to methylprednisolone (2 mg/kg loading dose, followed by 2 mg/kg divided into 4 times a day; taper within 7 days). If cerebral edema is suspected, consider hyperventilation and hyperosmolar therapy. Give high-dose methylprednisolone (1-2 g, repeat every 24 hours if needed; taper as clinically indicated) and cyclophosphamide 1.5 g/m2
Grade 4	Start non-sedating, antiseizure medicines (e.g., levetiracetam) for seizure prophylaxis. Start dexamethasone 20 mg IV every 6 hours. If no improvement after 24 hours or worsening of neurologic toxicity, escalate to high-dose methylprednisolone (1-2 g, repeated every 24 hours if needed; taper as clinically indicated). If cerebral edema is suspected, consider hyperventilation and hyperosmolar therapy. Give high-dose methylprednisolone (1-2 g, repeat every 24 hours if needed; taper as clinically indicated), and cyclophosphamide 1.5 g/m2

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REVISION LOG:

REVISIONS	DATE
Creation date	4/14/2022
Annual review	4/25/2023

Approved: Glendon Henry Digitally signed by Glendon Henry Date: 2023.04.26 07:44:16 -04'00' **Date:**	**Approved:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.04.26 09:06:41 -04'00' **Date:**
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.