
5.21.173

Section:	Prescription Drugs	Effective Date:	July 1, 2024
Subsection:	Antineoplastic Agents	Original Policy Date:	April 23, 2021
Subject:	Abecma	Page:	1 of 5

Last Review Date: June 13, 2024

Abecma

Description

Abecma (idecabtagene vicleucel)

Background

Abecma (idecabtagene vicleucel) 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 (1).

Regulatory Status

FDA-approved indication: Abecma is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (1).

Abecma has a boxed warning for cytokine release syndrome (CRS), neurological toxicities, Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), and prolonged cytopenia. Additionally, T cell malignancies have occurred following treatment with autologous T cell immunotherapies, including Abecma. Patients with an active infection or inflammatory disorders should not receive Abecma and monitoring for neurological events should be done after treatment with Abecma. HLH/MAS can occur with CRS or neurological toxicities. Prolonged cytopenia with bleeding and infection can occur following treatment with Abecma (1).

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Abecma is for autologous use only. A lymphodepleting chemotherapy regimen of cyclophosphamide and fludarabine should be administered before Abecma infusion (1).

Abecma is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Abecma REMS. Healthcare facilities that dispense and administer Abecma must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab (Actemra), and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within 2 hours after Abecma infusion, if needed for treatment of CRS (1).

Serious infections, including life-threatening or fatal infections, occurred in patients after Abecma infusion. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death can occur in patients treated with drugs directed against plasma cells. Perform screening for CMV, HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing (1).

The Celgene efficacy and safety study for Abecma excluded patients who had treatment with any gene therapy-based therapeutic for cancer or investigational cellular therapy for cancer or BCMA targeted therapy (2).

The safety and effectiveness of Abecma have not been established in pediatric patients (1).

Related policies

Carvykti

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Abecma may be considered **medically necessary** if the conditions indicated below are met.

Abecma may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

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Diagnosis

Patient must have the following:

1. Relapsed or refractory multiple myeloma

AND ALL of the following:

- a. Patient must have received **TWO** or more prior lines of therapy including:
 - i. Immunomodulatory agent
 - ii. Proteasome inhibitor
 - iii. Anti-CD38 monoclonal antibody
- b. Patient has adequate organ and bone marrow function as determined by the prescriber
- c. Absence of active infection (including TB, HBV, HCV, and HIV)
- d. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated
- e. Prescriber agrees to monitor the patient for signs and symptoms of cytokine release syndrome (CRS) and administer tocilizumab (Actemra) if needed
- f. Prescriber agrees to monitor the patient for signs and symptoms of neurological toxicities
- g. Administered in a healthcare facility enrolled in the Abecma REMS program
- h. **NO** prior therapy with any other gene therapy (e.g., Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta)
- i. **NO** dual therapy with any other gene therapy (e.g., Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta)

Prior – Approval *Renewal* Requirements

None

[Policy Guidelines](#)

Pre – PA Allowance

None

Prior - Approval Limits

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Quantity One infusion (only one PA approval for one infusion per lifetime)

Rationale

Summary

Abecma (idecabtagene vicleucel) 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. 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. Abecma has a boxed warning for cytokine release syndrome (CRS), neurological toxicities, Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), prolonged cytopenia, and T cell malignancies. Serious infections, including life-threatening or fatal infections, occurred in patients after Abecma infusion. The safety and effectiveness of Abecma have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Abecma while maintaining optimal therapeutic outcomes.

References

1. Abecma [package insert]. Summit, NJ: Bristol-Myers Squibb; April 2024.
2. Efficacy and Safety Study of bb2121 in Subjects with Relapsed and Refractory Multiple Myeloma. Celgene. NCT03361748. June 16, 2020.
3. NCCN Drugs & Biologics Compendium[®] Idecabtagene vicleucel 2024. National Comprehensive Cancer Network, Inc. Accessed on May 8, 2024.

Policy History

Date	Action
April 2021	Addition to PA
June 2021	Annual editorial review and reference update
March 2022	Annual review and reference update. Per FEP, added requirement that patient has adequate organ and bone marrow function as determined by the prescriber, and removed requirement of NO previous history of an allogenic hematopoietic stem cell transplantation
June 2022	Annual review and reference update. Addition of Carvykti to gene therapy requirement
October 2022	Per FEP, removed duration from PA

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December 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update
May 2024	Per PI update, requirement of 4 prior lines of therapy reduced to 2 prior lines. Add boxed warning update regarding T cell malignancy risk to regulatory section
June 2024	Annual review and reference update

[Keywords](#)

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.