Clinical Policy: Idecabtagene Vicleucel (Abecma)

Reference Number: ERX.SPA.394
Effective Date: 03.26.21
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Idecabtagene vicleucel (Abecma®) is an anti-B cell maturation antigen (BCMA) chimeric antigen receptor (CAR) T-cell immunotherapy.

FDA Approved Indication(s)
Abecma is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Abecma is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma* (must meet all)**:**
**Only for initial treatment dose; subsequent doses will not be covered.*

1. Diagnosis of multiple myeloma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Member has measureable disease as evidenced by one of the following assessed within the last 30 days (a, b, or c):
   a. Serum M-protein ≥ 1 g/dL;
   b. Urine M-protein ≥ 200 mg/24 h;
   c. Serum free light chain (FLC) assay: involved FLC level ≥ 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal;
5. Member has received ≥ 4 prior lines of therapy (*see Appendix B for examples*) that include all of the following (a, b, and c):
   a. One immunomodulatory agent (e.g., Revlimid®, pomalidomide, Thalomid®);
   b. One proteasome inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®);
   c. One anti-CD38 antibody (e.g., Darzalex®/Darzalex Faspro™, Sarclisa®);
   **Prior authorization may be required. Induction with or without hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen.*
6. Member does not have active central nervous system (CNS) disease;
7. Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Breyanzi™, Kymriah™, Tecartus™, Yescarta™);
8. Abecma is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Breyanzi, Kymriah, Tecartus, Yescarta);
9. Dose does not exceed 460 CAR-positive T-cells.

Approval duration: 3 months *(1 dose only, with 4 doses of tocilizumab (Actemra) if requested at up to 800 mg per dose)*

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Multiple Myeloma
1. Continued therapy will not be authorized as Abecma is indicated to be dosed one time only.

Approval duration: Not applicable

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Active CNS disease.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCMA: B-cell maturation antigen
CAR: chimeric antigen receptor
CNS: central nervous system
FDA: Food and Drug Administration
FLC: free light chain

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bortezomib/Revlimid® (lenalidomide) /dexamethasone	Varies	Varies
bortezomib/cyclophosphamide/dexamethasone	Varies	Varies
bortezomib/doxorubicin (or liposomal doxorubicin)/dexamethasone	Varies	Varies
Kyprolis® (carfilzomib)/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Kyprolis® (carfilzomib)/cyclophosphamide/dexamethasone	Varies	Varies
Kyprolis® (carfilzomib – weekly or twice weekly)/dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/pomalidomide/dexamethasone	Varies	Varies
bortezomib/dexamethasone	Varies	Varies
bortezomib/Thalomid® (thalidomide)/dexamethasone	Varies	Varies
cyclophosphamide/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
VTD-PACE (dexamethasone/Thalomid® (thalidomide)/cisplatin/doxorubicin/ cyclophosphamide/etoposide/bortezomib)	Varies	Varies
Revlimid® (lenalidomide)/low-dose dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/bortezomib/melphan/ prednisone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/bortezomib/dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/pomalidomide/ dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/bortezomib/dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/pomalidomide/dexamethasone	Varies	Varies
bendamustine/bortezomib/dexamethasone	Varies	Varies
bendamustine/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
panobinostat/bortezomib/dexamethasone	Varies	Varies
panobinostat/Kyprolis® (carfilzomib)	Varies	Varies
panobinostat/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
pomalidomide/cyclophosphamide/dexamethasone	Varies	Varies
pomalidomide/dexamethasone	Varies	Varies
pomalidomide/bortezomib/dexamethasone	Varies	Varies
pomalidomide/ Kyprolis® (carfilzomib)/ dexamethasone	Varies	Varies
Sarclisa® (isatuximab-irfc)/pomalidomide/dexamethasone	Varies	Varies
Xpovio® (selinexor)/bortezomib/dexamethasone	Varies	Varies
Xpovio® (selinexor)/Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/dexamethasone	Varies	Varies
Xpovio® (selinexor)/pomalidomide/dexamethasone	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): cytokine release syndrome, neurologic toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, and prolonged cytopenia

Appendix D: General Information

- Patients with CNS involvement with their multiple myeloma were excluded from the pivotal KarMMa trial.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Multiple myeloma	Single IV infusion; target dose: 300-460 x 10^6 CAR-positive T-cells	460 x 10^6 CAR-positive T-cells

VI. Product Availability

Single-dose unit infusion bag: frozen suspension of genetically modified autologous T-cells labeled for the specific recipient

VII. References

1. Abecma Prescribing Information. Summit, NJ: Celgene Corporation; March 2021. Available at: https://www.abecma.com. Accessed March 29, 2021.
2. Efficacy and safety study of bb2121 in subjects with relapsed and refractory multiple myeloma (KarMMa). Available at: https://clinicaltrials.gov/ct2/show/NCT03361748. Accessed March 29, 2021.
3. 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.
4. Raje N, Berdeja J, Lin Y, et al. Anti-BCMA CAR T-cell therapy bb2121 in relapsed or refractory multiple myeloma. N Engl J Med. 2019; 380(18): 1726-1737.

5. National Comprehensive Cancer Network. Multiple Myeloma Version 6.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed April 13, 2021.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 13, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	04.21.20	05.20
Clarified Actemra authorization may be considered if requested.	03.18.21	
2Q 2021 annual review: drug is now FDA approved - criteria updated per FDA labeling: revised from 3 prior therapies to 4 prior therapies; references reviewed and updated.	04.13.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.