

Clinical Policy: Idecabtagene Vicleucel (Abecma)

Reference Number: PA.CP.PHAR.481

Effective Date: 07/2021

Last Review Date: 04/2024

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 after four or more 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.

All requests reviewed under this policy **require medical director review**.

It is the policy of PA Health & Wellness[®] 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 relapsed or refractory multiple myeloma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age \geq 18 years;
4. One of the following (a or b):
 - a. Member has measureable disease as evidenced by one of the following assessed within the last 30 days (i, ii, or iii):
 - i. Serum M-protein \geq 1 g/dL;
 - ii. Urine M-protein \geq 200 mg/24 h;
 - iii. Serum free light chain (FLC) assay: involved FLC level \geq 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal;
 - b. Member has progressive disease, as defined by the IMWG response criteria (see *Appendix D*), assessed within 60 days following the last dose of the last anti-myeloma drug regimen received;
5. Member has received \geq 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[®], Pomalyst[®], 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 anti-BCMA targeted therapy (e.g., Blenrep™, Tecvayli™);
8. Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Breyanzi™, Kymriah™, Tecartus™, Yescarta™);
9. Abecma is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Breyanzi, Kymriah, Tecartus, Yescarta);
10. Dose does not exceed 510 x 10⁶ 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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 policies – PA.CP.PMN.53;
- B.** Known CNS involvement with myeloma, or history or presence of clinically relevant CNS pathology (e.g., epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis).

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

IMWG: International Myeloma Working Group

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 (e.g., epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis).
- The IMWG response criteria for multiple myeloma definition of progressive disease requires only one of the following:
 - Increase of 25% from lowest response value in any of the following:
 - Serum M-component (absolute increase must be ≥ 0.5 g/dL), and/or
 - Urine M-component (absolute increase must be ≥ 200 mg/24 h), and/or
 - Only in patients without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels (absolute increase must be > 10 mg/dL)
 - Only in patients without measurable serum and urine M protein levels and without measurable disease by FLC levels, bone marrow plasma cell percentage irrespective of baseline status (absolute increase must be $\geq 10\%$)
 - Appearance of a new lesion(s), $\geq 50\%$ increase from nadir in SPD (sum of the products of the maximal perpendicular diameters of measured lesions) of > 1 lesion, or $\geq 50\%$ increase in the longest diameter of a previous lesion >1 cm in short axis;
 - $\geq 50\%$ increase in circulating plasma cells (minimum of 200 cells per μL) if this is the only measure of disease

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
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Multiple myeloma	Single IV infusion; target dose: 300-460 x 10 ⁶ CAR-positive T cells	460 x 10 ⁶ CAR-positive T-cells
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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; January 2024. Available at: <https://www.abecma.com>. Accessed January 9, 2024.
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 January 22, 2024.
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 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed January 22, 2024.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 22, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	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

Reviews, Revisions, and Approvals	Date
Policy created	07/2021
2Q 2022 annual review: updated HCPCS codes; references reviewed and updated.	04/2022
2Q 2023 annual review: added additional option to currently required measurable disease requirement to allow for progressive disease as defined by IMWG; clarified requirement for diagnosis of <i>relapsed or refractory</i> multiple myeloma; references reviewed and updated.	04/2023
2Q 2024 annual review: no significant changes; update excluded CNS involvement with myeloma; references reviewed and updated.	04/2024