



ABECMA® Coding & Billing Information

For questions about coding & billing information,
call Cell Therapy 360® at 1-888-805-4555

INDICATION

ABECMA (idecabtagene vicleuce) 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 four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, AND PROLONGED CYTOPENIA

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with ABECMA. Do not administer ABECMA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic Toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with ABECMA. Provide supportive care and/or corticosteroids as needed.**
- **Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS) including fatal and life-threatening reactions, occurred in patients following treatment with ABECMA. HLH/MAS can occur with CRS or neurologic toxicities.**
- **Prolonged Cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with ABECMA.**
- **ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.**

This information is provided for educational purposes only. Bristol Myers Squibb cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care, and is subject to frequent change. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please see Important Safety Information on pages 11-14 and full [Prescribing Information](#), including **Boxed WARNINGS** and [Medication Guide](#).



ABECMA® is the first CAR T cell therapy for relapsed/refractory multiple myeloma (RRMM).¹ 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 four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.¹ ABECMA is for autologous use only and is administered intravenously, as a one-time infusion.^{1,*} ABECMA is provided as a single dose for infusion containing a suspension of CAR-positive T cells in one or more infusion bags. The recommended dose range is 300 to 460 x 10⁶ CAR-positive T cells.¹ Coding and billing for CAR T cell therapies will vary based on each patient’s condition, provided services, payer-specific requirements, and selected site/setting of care. Use this guide to review relevant codes and sample claim forms for ABECMA.

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CAR T = chimeric antigen receptor-modified T cell; CMS = Centers for Medicare and Medicaid Services; CPT = Current Procedural Terminology; HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS = International Classification of Diseases, Tenth Revision, Procedure Coding System; NDC = National Drug Code.

* Treatment process includes leukapheresis, drug manufacturing, administration, and adverse event monitoring.

Please see Important Safety Information on pages 11-14 and full Prescribing Information, including Boxed WARNINGS and Medication Guide.



ICD-10-CM Diagnosis Codes

The ICD-10-CM codes listed below for the approved indication for ABECMA® are provided by Bristol Myers Squibb and should be verified with a patient’s payer. Some payers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record.

ICD-10-CM Code ²	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
Z00.6*	Encounter for examination for normal comparison and control in clinical research program
Z51.12	Encounter for antineoplastic immunotherapy

* This code should be reported only for clinical trial cases. In the event that the CAR T product is purchased in the usual manner but is being used for a clinical trial involving a different product (ie, the clinical trial is for a non-CAR T product), the provider may enter a Billing Note NTE02 (“Diff Prod Clin Trial”) on the electronic claim form (or a remark “Diff Prod Clin Trial” on a paper claim). To notify Medicare of expanded access use (EAU) of a CAR T product, the provider may enter a Billing Note NTE02 “Expand Acc Use” on the electronic claim (or a remark “Expand Acc Use” on a paper claim).

**For questions about coding & billing information,
call Cell Therapy 360® Patient Support at 1-888-805-4555**

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb makes no guarantee regarding reimbursement for any service or item.

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HCPCS Level II Product Codes

Effective October 1, 2021, ABECMA has been assigned a temporary C-code and a transitional pass-through status under the Medicare FFS Outpatient Prospective Payment System (OPPS).³ Products with a pass-through status are not subject to the payment adjustment for 340B-acquired drugs (status indicator G); reimbursement is based on ASP plus 6% (or WAC plus 3% when ASP is not available). Transitional pass-through status is typically granted for up to 3 years.⁴

HCPCS Code ³	Description	Notes
C9081	Idecabtagene vicleucel, up to 460 million autologous anti-BCMA CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	FOR MEDICARE FFS*: <ul style="list-style-type: none"> • Required for claims billed by outpatient hospital facilities under the OPPS for services performed on or after October 1, 2021^{5,*†} • 1 billing unit
J3490	Unclassified drugs	FOR OTHER PAYERS AND/OR SITES OF CARE: <ul style="list-style-type: none"> • Additional information is typically required, including: <ul style="list-style-type: none"> – Product name – Dosage – NDC number – Route of administration • Requirements may vary; refer to the specific payer policy
J3590	Unclassified biologics	

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ASP = average sales price; FFS = fee-for-service; HCPCS = Healthcare Common Procedure Coding System; NDC = National Drug Code; WAC = wholesale acquisition cost.

* Some commercial and Medicare Advantage plans may also require C9081 for ABECMA claims; refer to specific payer policies as billing requirements may vary.

† For Medicare FFS claims billed by outpatient hospital facilities under the OPPS, including those billed by off-campus provider-based departments (PBDs), TB modifier should be reported if ABECMA has been acquired under the 340B drug pricing program.^{5,6}

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NDC Information

ABECMA[®] is provided as a single dose for infusion containing a suspension of CAR-positive T cells in one or more infusion bags. The recommended dose range is 300 to 460 x 10⁶ CAR-positive T cells.¹ ABECMA is supplied in one or more infusion bag(s) containing a frozen suspension of genetically modified autologous T cells in 5% dimethyl sulfoxide (DMSO) concentration.¹ Each infusion bag of ABECMA (supplied in one of three sizes) is individually packed in a metal cassette. Please note that ABECMA is an autologous product; the manufactured dose, as well as the corresponding number and size of ABECMA infusion bags, for individual patients, may vary.

Bag Size and Description ¹	10-digit Format ¹	11-digit Format
50 mL infusion bag and metal cassette	59572-515-01	59572-0515-01
250 mL infusion bag and metal cassette	59572-515-02	59572-0515-02
500 mL infusion bag and metal cassette	59572-515-03	59572-0515-03

Payers may require that NDC number(s) is (are) documented on medical claims submitted for provider-administered therapies, including drugs and biologics billed with an unclassified/miscellaneous code or those with an assigned code.

Specific requirements for NDC reporting may vary; however, the 11-digit format is generally preferred for medical claims. Some payers may require reporting the 11-digit NDC number, along with the NDC qualifier, basis of measure, and quantity.⁷ For example, ABECMA NDC number(s) reported in this format would include:

NDC Qualifier	11-digit NDC	Quantity Qualifier	Quantity for a Single Dose
N4	59572-0515-01 59572-0515-02 59572-0515-03	UN	1

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ICD-10-PCS Inpatient Procedure Codes*

Effective for discharges on or after October 1, 2021, the following CAR T-designated ICD-10-PCS codes may be reported for inpatient facility services associated with ABECMA administration.

ICD-10-PCS Code ⁸	Description	Notes for Medicare FFS Under the IPPS [†]
XW033K7	Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	For FY 2022: <ul style="list-style-type: none"> Assigned to MS-DRG 018 (Chimeric Antigen Receptor [CAR] T cell and Other Immunotherapies), with the average national base payment rate of \$246,957 (the exact rate may vary widely based on hospital-specific adjustments)^{8,9,‡} Eligible for NTAP, the amount of which will be determined on a case-by-case basis and will not exceed \$272,675^{8,§}
XW043K7	Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7	

FY = fiscal year; ICD-10-PCS = International Classification of Diseases, Tenth Revision, Procedure Coding System; IPPS = Inpatient Prospective Payment System; MS-DRG = Medicare Severity Diagnosis Related Group.

* Site/Setting of care decisions are the sole discretion of the treating physician.

[†] For Medicare Advantage patients, billing requirements and reimbursement methodology may vary by plan.

[‡] The estimated average does not include outlier, new technology add-on payment (NTAP), pass-through payments, or other applicable hospital-specific adjustments.

[§] NTAP amount for eligible ABECMA cases will be determined based on a hospital's reported charges and its cost-to-charge ratio (CCR). It will equal the lesser of the following—65% of estimated CAR T cost (ie, \$272,675) or 65% of the difference between the estimated case cost and the hospital's base rate for MS-DRG 018.⁸

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb makes no guarantee regarding reimbursement for any service or item.

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Hospital Revenue Codes*

The following CAR T-designated revenue codes may be reported with accompanying line items billed for services associated with ABECMA®.

Revenue Code ¹⁰	Description	Notes for Medicare FFS [†]
0871	Cell/gene therapy – cell collection	Charges for services associated with cell collection and cell processing/storage can be reported under 0871, 0872, and 0873, as separate line items for tracking purposes only. Alternatively, these charges can be reported with ABECMA charges under 0891, as a single line item. ^{11,†,‡}
0872	Cell/gene therapy – specialized biologic processing and storage – prior to transport	
0873	Cell/gene therapy – storage and processing after receipt of cells from manufacturer	
0874	Cell/gene therapy – infusion of modified cells	
0891	Pharmacy – specialized processed drugs – FDA approved cell therapy	

* Site/Setting of care decisions are the sole discretion of the treatment physician.

† For Medicare FFS patients, when the charges for collection and preparation of the CAR T cells are included with the charges for the CAR T product (as a single line item under 0891), the reported date of service must be based on the date of CAR T administration. When cell collection and/or cell processing/storage services are initiated and furnished in the hospital outpatient setting, but the CAR T cell therapy is administered in the inpatient setting, all related charges must be reported on the inpatient claim with the date of CAR T administration as the date of service (reported as separate line items for tracking purposes under 0871, 0872, and 0873 or as a single line item along with CAR T product charges under 0891). For more information, please see Medicare Transmittal 10891.¹²

‡ For Medicare FFS patients, 3-day payment window policy applies to outpatient services furnished by a hospital or an entity wholly owned or wholly operated by the hospital. Note that for IPPS-exempt hospitals, 1-day payment window applies.¹³

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb makes no guarantee regarding reimbursement for any service or item.

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CPT® Codes for Outpatient Hospital Services*

The following CAR T-designated CPT Category III codes may be reported for outpatient hospital facility services associated with ABECMA®. Please note that only one of these CPT Category III codes (CPT code 0540T) is separately payable by Medicare under the Hospital Outpatient Prospective Payment System (OPPS).^{5,14}

CMS has not assigned relative value units or APCs to these Category III CPT codes, with the exception of the CPT code 0540T under the OPPS.¹⁴ As such, they may not be payable by non-Medicare payers.

CPT Category III Code ⁵	Description	Corresponding Hospital Revenue Code ^{10,†}	Medicare FFS Reimbursement Status Under OPPS in CY 2021 ^{5,14,‡}
Apheresis and Preparation			
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	0871	Not recognized by OPPS [§] (status indicator B)
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)	0872	
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration	0873	
Administration			
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous	0874	Paid under APC 5694 (status indicator S, CY 2021 national average payment rate is \$310.75)

APC = Ambulatory Payment Classification; CY = calendar year.

* Site/Setting of care decisions are the sole discretion of the treating physician/institution.

† See previous page for revenue code descriptions.

‡ For Medicare Advantage patients, billing requirements and reimbursement methodology may vary by plan.

§ CPT Category III codes 0537T, 0538T, and 0539T can be reported for tracking purposes only, as non-covered charges. For more information, please see Medicare Transmittal 10891.¹²

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Sample CMS 1450 (UB-04) Claim Form For Inpatient Hospital Facilities¹⁵

The form is a CMS 1450 (UB-04) Claim Form for Inpatient Hospital Facilities. It contains various fields for patient information, diagnosis codes, procedure codes, charges, and insurance details. Callouts 4, 42, 43, 44, 45, 46, 47, 67, 74, and 80 point to specific fields: 4 (Statement Covers Period), 42 (Occurrence Code), 43 (Description), 44 (HCPCS Code), 45 (Service Date), 46 (Units), 47 (Total Charges), 67 (ICD-10-CM Code), 74 (Principal Procedure Code), and 80 (Remarks).

4 FL 4: Enter the appropriate type of bill code. For example¹⁶:

- 0111 for an inpatient hospital facility

42 FL 42: Enter the appropriate revenue code for each reported line. For example^{10,11}:

- 0874 for CAR T infusion
- 0891 for ABECMA[®]

43 FL 43: Enter the description for the corresponding revenue code in FL 42.

NOTE: Some payers may require to report drug NDC number in FL 43; specific NDC reporting requirements may vary. The NDC number for ABECMA will be based on the size of the supplied infusion bag(s) - 59572-0515-01 for the 50-mL infusion bag(s), 59572-0515-02 for the 250-mL infusion bag(s), 59572-0515-03 for the 500-mL infusion bag(s).

44 FL 44: If required by payer, enter relevant HCPCS Level II code, along with the applicable modifier. For example^{3,5}:

- 0540T for CAR T infusion
- C9081, J3490, or J3590 for ABECMA

45 FL 45: Enter corresponding date(s) of service.

46 FL 46: Enter appropriate units of service.

NOTE: For C9081, 1 unit of service is reported per therapeutic dose of ABECMA.³ For miscellaneous codes, such as J3490 and J3590, 1 unit of service is typically reported.¹⁷

47 FL 47: Enter total charges for each reported line.

67 FL 67: Enter appropriate ICD-10-CM diagnosis code(s) for patient condition(s). For example²:

- C90.02 for multiple myeloma in relapse

74 FL 74: Enter relevant ICD-10-PCS procedure code(s) with corresponding date(s) of service. For example, for ABECMA infusion⁸:

- XW033K7 or XW043K7

80 FL 80: Enter product information required when reporting a miscellaneous code (eg, drug name, dosage [number of CAR-positive T cells per infusion], NDC number, route of administration).⁴

NOTE: The NDC number for ABECMA will be based on the size of the supplied infusion bag(s) - 59572-0515-01 for the 50-mL infusion bag(s), 59572-0515-02 for the 250-mL infusion bag(s), 59572-0515-03 for the 500-mL infusion bag(s).

Requirements may vary;
refer to specific payer policy*

* Billing instructions have been issued for Medicare FFS patients. For more information, please see Medicare Transmittal 10891.¹²

These sample forms are for informational purposes only. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb makes no guarantee regarding reimbursement for any service or item.

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Sample CMS 1450 (UB-04) Claim Form For Outpatient Hospital Facilities¹⁵

The image shows a sample CMS 1450 (UB-04) Claim Form for Outpatient Hospital Facilities. The form is annotated with yellow callout boxes containing numbers 4, 42, 43, 44, 45, 46, 47, 67, and 80, which correspond to the 'FL' (Field Label) definitions provided on the right. The form includes sections for patient information, procedure codes, charges, and insurance details. The 'REMARKS' section (80) contains text: 'ABECMA (idecabtagene vicleuce), single dose containing X CAR-positive T cells, NDC 59572-0515-01, IV infusion'.

- 4** FL 4: Enter the appropriate type of bill code. For example¹⁶:
 - 0131 for an outpatient hospital facility
- 42** FL 42: Enter the appropriate revenue code for each reported line. For example^{10,11}:
 - 0874 for CAR T infusion
 - 0891 for ABECMA[®]
- 43** FL 43: Enter the description for the corresponding revenue code in FL 42.

NOTE: Some payers may require to report drug NDC number in FL 43; specific NDC reporting requirements may vary. The NDC number for ABECMA will be based on the size of the supplied infusion bag(s) - 59572-0515-01 for the 50-mL infusion bag(s), 59572-0515-02 for the 250-mL infusion bag(s), 59572-0515-03 for the 500-mL infusion bag(s).
- 44** FL 44: If required by payer, enter relevant HCPCS Level II code, along with the applicable modifier. For example^{3,5}:
 - 0540T for CAR T infusion
 - C9081, J3490, or J3590 for ABECMA
- 45** FL 45: Enter corresponding date(s) of service.
- 46** FL 46: Enter appropriate units of service.

NOTE: For C9081, 1 unit of service is reported per therapeutic dose of ABECMA.³ For miscellaneous codes, such as J3490 and J3590, 1 unit of service is typically reported.¹⁷
- 47** FL 47: Enter total charges for each reported line.
- 67** FL 67: Enter appropriate ICD-10-CM diagnosis code(s) for patient condition(s). For example²:
 - C90.02 for multiple myeloma in relapse
- 80** FL 80: Enter product information required when reporting a miscellaneous code (eg, drug name, dosage [number of CAR-positive T cells per infusion], NDC number, route of administration).⁴

NOTE: The NDC number for ABECMA will be based on the size of the supplied infusion bag(s) - 59572-0515-01 for the 50-mL infusion bag(s), 59572-0515-02 for the 250-mL infusion bag(s), 59572-0515-03 for the 500-mL infusion bag(s).

Requirements may vary;
refer to specific payer policy*

* Billing instructions have been issued for Medicare FFS patients. For more information, please see Medicare Transmittal 10891.¹²

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INDICATION

ABECMA® (idecabtagene vicleucel) 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 four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, AND PROLONGED CYTOPENIA

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with ABECMA. Do not administer ABECMA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic Toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with ABECMA. Provide supportive care and/or corticosteroids as needed.**
- **Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS) including fatal and life-threatening reactions, occurred in patients following treatment with ABECMA. HLH/MAS can occur with CRS or neurologic toxicities.**
- **Prolonged Cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with ABECMA.**
- **ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.**

Warnings and Precautions:

Cytokine Release Syndrome (CRS)

CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA in 85% (108/127) of patients. Grade 3 or higher CRS occurred in 9% (12/127) of patients, with Grade 5 CRS reported in one (0.8%) patient. The median time to onset of CRS, any grade, was 1 day (range: 1 - 23 days) and the median duration of CRS was 7 days (range: 1 - 63 days). The most common manifestations included pyrexia, hypotension, tachycardia, chills, hypoxia, fatigue, and headache. Grade 3 or higher events that may be associated with CRS include hypotension, hypoxia, hyperbilirubinemia, hypofibrinogenemia, acute respiratory distress syndrome (ARDS), atrial fibrillation, hepatocellular injury, metabolic acidosis, pulmonary edema, multiple organ dysfunction syndrome, and HLH/MAS.

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Please see full [Prescribing Information](#), including **Boxed WARNINGS** and **Medication Guide**.

IMPORTANT SAFETY INFORMATION (cont'd)

Cytokine Release Syndrome (CRS) (cont'd)

Fifty four percent (68/127) of patients received tocilizumab (single dose: 35%; more than 1 dose: 18%). Overall, 15% (19/127) of patients received at least 1 dose of corticosteroids for treatment of CRS. All patients that received corticosteroids for CRS received tocilizumab. Ensure that a minimum of 2 doses of tocilizumab are available prior to infusion of ABECMA.

Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of CRS and monitor patients for signs or symptoms of CRS for at least 4 weeks after ABECMA infusion. At the first sign of CRS, institute treatment with supportive care, tocilizumab and/or corticosteroids as indicated.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurologic Toxicities

Neurologic toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA in 28% (36/127) of patients receiving ABECMA, including Grade 3 in 4% (5/127) of patients. One patient had ongoing Grade 2 neurotoxicity at the time of death. Two patients had ongoing Grade 1 tremor at the time of data cutoff. The median time to onset of neurotoxicity was 2 days (range: 1 - 42 days). CAR T cell-associated neurotoxicity resolved in 92% (33/36) of patients with a median time to resolution of 5 days (range: 1 - 61 days). The median duration of neurotoxicity was 6 days (range: 1 - 578) in all patients including 3 patients with ongoing neurotoxicity. Thirty-four patients with neurotoxicity had CRS with onset in 3 patients before, 29 patients during, and 2 patients after CRS. The most frequently reported manifestations of CAR T cell-associated neurotoxicity include encephalopathy, tremor, aphasia, and delirium. Grade 4 neurotoxicity and cerebral edema in 1 patient, Grade 3 myelitis, and Grade 3 parkinsonism have been reported with ABECMA in another study in multiple myeloma.

Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of neurologic toxicities and monitor patients for signs or symptoms of neurologic toxicities for at least 4 weeks after ABECMA infusion and treat promptly. Rule out other causes of neurologic symptoms. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Counsel patients to seek immediate medical attention should signs or symptoms occur at any time.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS)

HLH/MAS occurred in 4% (5/127) of patients receiving ABECMA. One patient developed fatal multi-organ HLH/MAS with CRS and another patient developed fatal bronchopulmonary aspergillosis with contributory HLH/MAS. Three cases of Grade 2 HLH/MAS resolved. All events of HLH/MAS had onset within 10 days of receiving ABECMA with a median onset of 7 days (range: 4 - 9 days) and occurred in the setting of ongoing or worsening CRS. Two patients with HLH/MAS had overlapping neurotoxicity. The manifestations of HLH/MAS include hypotension, hypoxia, multiple organ dysfunction, renal dysfunction, and cytopenia. HLH/MAS is a potentially life-threatening condition with a high mortality rate if not recognized early and treated. Treatment of HLH/MAS should be administered per institutional guidelines.

Please see full [Prescribing Information](#), including **Boxed WARNINGS** and **Medication Guide**.

IMPORTANT SAFETY INFORMATION (cont'd)

ABECMA REMS

Due to the risk of CRS and neurologic toxicities, ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS. Further information is available at www.AbecmaREMS.com or 1-888-423-5436.

Hypersensitivity Reactions

Allergic reactions may occur with the infusion of ABECMA. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) in ABECMA.

Infections

ABECMA should not be administered to patients with active infections or inflammatory disorders. Severe, life-threatening, or fatal infections occurred in patients after ABECMA infusion. Infections (all grades) occurred in 70% of patients. Grade 3 or 4 infections occurred in 23% of patients. Overall, 4 patients had Grade 5 infections (3%); 2 patients (1.6%) had Grade 5 events of pneumonia, 1 patient (0.8%) had Grade 5 bronchopulmonary aspergillosis, and 1 patient (0.8%) had cytomegalovirus (CMV) pneumonia associated with *Pneumocystis jirovecii*. Monitor patients for signs and symptoms of infection before and after ABECMA infusion and treat appropriately. Administer prophylactic, pre-emptive, and/or therapeutic antimicrobials according to standard institutional guidelines.

Febrile neutropenia was observed in 16% (20/127) of patients after ABECMA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care.

Viral Reactivation: CMV infection resulting in pneumonia and death has occurred following ABECMA administration. Monitor and treat for CMV reactivation in accordance with clinical guidelines. 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, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines before collection of cells for manufacturing.

Prolonged Cytopenias

In the clinical study, 41% of patients (52/127) experienced prolonged Grade 3 or 4 neutropenia and 49% (62/127) experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Month 1 following ABECMA infusion. In 83% (43/52) of patients who recovered from Grade 3 or 4 neutropenia after Month 1, the median time to recovery from ABECMA infusion was 1.9 months. In 65% (40/62) of patients who recovered from Grade 3 or 4 thrombocytopenia, the median time to recovery was 2.1 months.

Three patients underwent stem cell therapy for hematopoietic reconstitution due to prolonged cytopenia. Two of the three patients died from complications of prolonged cytopenia. Monitor blood counts prior to and after ABECMA infusion. Manage cytopenia with myeloid growth factor and blood product transfusion support.

Please see full [Prescribing Information](#), including **Boxed WARNINGS** and **Medication Guide**.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypogammaglobulinemia

Hypogammaglobulinemia was reported as an adverse event in 21% (27/127) of patients; laboratory IgG levels fell below 500 mg/dl after infusion in 25% (32/127) of patients treated with ABECMA.

Monitor immunoglobulin levels after treatment with ABECMA and administer IVIG for IgG <400 mg/dl. Manage appropriately per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

The safety of immunization with live viral vaccines during or after ABECMA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during ABECMA treatment, and until immune recovery following treatment with ABECMA.

Secondary Malignancies

Patients treated with ABECMA may develop secondary malignancies. Monitor life-long for secondary malignancies. If a secondary malignancy occurs, contact Bristol Myers Squibb at 1-888-805-4555 to obtain instructions on patient samples to collect for testing of secondary malignancy of T cell origin.

Effects on Ability to Drive and Operate Machinery

Due to the potential for neurologic events, patients receiving ABECMA are at risk for altered or decreased consciousness or coordination in the 8 weeks following ABECMA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

Adverse Reactions

The most common nonlaboratory adverse reactions include CRS, infections – pathogen unspecified, fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite.

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Please see Important Safety Information on pages 11-14 and full [Prescribing Information](#), including **Boxed WARNINGS** and [Medication Guide](#).

