Abecma is a chimeric antigen receptor T cell therapy (CAR-T), designed to harness the power of the patient’s immune system to recognize and attack their cancer cells. CAR-T is a type of treatment where white blood cells (T cells) are modified in a laboratory to add a gene that helps the patient’s own T cells target their cancer.

**FDA-Approved Indication**
Abecma is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy for the treatment of:

- Adult patients with relapsed or refractory multiple myeloma after four or more lines of systemic therapy including at least one drug from each of the following categories:
  - Immunomodulatory agent
  - Proteasome inhibitor
  - Anti-CD38 monoclonal antibody

**Criteria**
1. **Criteria for Initial Approval**
   Authorization of a single treatment may be granted to patients 18 years of age or older for treatment of multiple myeloma when ALL of the following criteria are met:
   A. The disease is relapsed or refractory to treatment after four or more lines of systemic therapy.
   B. The patient did not receive a previous treatment course of the requested medication or another B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T-cell therapy.
   C. The patient does not have active infections or inflammatory disorders.
   D. The healthcare facility that dispenses and administers Abecma must be enrolled and comply with the Abecma Risk Evaluation and Mitigation Strategy known as REMS.
   E. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.

2. **Required Documentation**
   - Confirmed diagnosis and clinical features of the diagnosis (including laboratory results confirming the diagnosis), relevant history and physical and prior cancer treatment history.
   - Documentation of four prior lines of therapy
   - Provider/patient REMS certification/enrollment

3. **Duration of Therapy**
• Single treatment course
• Additional courses of therapy are considered experimental/investigational.

**CPT/HCPCS Codes**

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<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<td>J9999</td>
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**NDC Information**

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**Effective**

September 2021: Effective Date.

**References**

