

Blue Distinction® Centers for Cellular Immunotherapy CAR-T Therapy Selection Criteria

Blue Distinction®

Blue Distinction is a national designation awarded by Blue Cross Blue Shield (BCBS) Plans to recognize providers that demonstrate expertise in delivering quality specialty care – safely, effectively, and cost-efficiently. The goal of the program is to help patients find both quality and value for their specialty care needs, while providing a credible foundation on which employers may customize their employee benefits. Distinction in local communities and nationwide.

Blue Distinction Centers for Cellular Immunotherapy - CAR-T Therapy

The Blue Distinction Centers for Cellular Immunotherapy program (Program) aims to improve patient outcomes and cost for members undergoing chimeric antigen receptor T cell (CAR-T) therapies, which are genetically-modified autologous T cell immunotherapies that may bring new treatment options for certain cancer patients. The treatment involves genetic re-engineering of a patient's white blood cells, and two CAR-T therapies have been recently approved by the FDA to treat certain patients with Leukemia (Kymriah™) and Lymphoma (Yescarta™ and Kymriah). The complexity and expertise needed to deliver these treatments supports identifying centers of excellence, through this Program. Providers that have been identified by a product manufacturer certification program to deliver CAR-T therapy will be invited to participate in this Blue Distinction Program's evaluation process. The Program will continue to expand in the future, as new CAR-T treatments become FDA approved.

Since these new CAR-T therapies have been recently introduced into clinical use, current insight into the episode of care and optimal clinical pathways is limited. As the Blue Distinction program and its selection criteria evolve, we will continue to work with the medical community to identify meaningful clinical measures of quality and establish outcomes data to guide quality improvement for patient care.

Designation as a Blue Distinction Center for Cellular Immunotherapy differentiates providers locally, as well as nationally. This highly respected designation acknowledges the expertise providers have demonstrated and their commitment to improving quality and affordability. Designations are awarded based on quality criteria that support delivery of timely, coordinated, multidisciplinary, evidence based care with a focus on quality improvement and patient-centered care. To be considered for the Blue Distinction Centers for Cellular Immunotherapy – CAR-T Therapy designation, a provider must:

- meet 13 Quality Criteria;
- meet Business Criteria;
- meet Value Criteria for specialty pharmacy product; and
- meet Local Blue Plan Criteria, if applicable.

Quality Criteria

“**CAR-T Episode of Care**,” as used herein, includes: (1) pre-CAR-T therapy, which begins with leukapheresis; (2) conditioning for CAR-T therapy, which occurs prior to initiation of CAR-T cell infusion; (3) CAR-T cell infusion, acute phase recovery, monitoring, and management, for 30 days after CAR-T cell infusion; and (4) monitoring outcomes, managing any complications, and providing ongoing support during later phase follow up.

“**CAR-T Episode of Care**” pertains to CAR-T therapy using **either** of the currently FDA-approved products (Kymriah or Yescarta).

Blue Distinction Centers for Cellular Immunotherapy – CAR-T Therapy		
Quality Criteria Category	Definition	Selection Criteria
Delivery	Accessibility to timely, multi-disciplinary, coordinated CAR-T therapy care	1. Delivers coordinated multidisciplinary care, including facilitating timely access to quality medical and psychosocial care, throughout CAR-T Episode of Care.
		2. Delivers efficient, appropriate, and effective flow of necessary patient care information to providers and patients (e.g., use of EHR and patient portal).
		3. Delivers care planning by managing patients throughout all stages of treatment during CAR-T Episode of Care.
		4. Facilitates multidisciplinary care (either within an integrated delivery system or through coordination within a virtually organized ‘medical neighborhood’ delivery system), to ensure that the patient has access to all of the following disciplines: <ul style="list-style-type: none"> • Medical Oncology; • Nursing/Oncology Nursing; • Palliative Care; • Diagnostic Radiology; • Pathology; • Genetic Counseling; • Social Work/Psychosocial Support; and • Rehabilitation
		5. Ensures enhanced care access (open access scheduling, expanded hours, and new options for communication between patient and practice) to support urgent patient needs.
Quality	Commitment to providing safe, evidence-based, patient-centered care	6. Program is certified to provide CAR-T therapy through at least one of the REMS programs offered by Novartis or Kite.
		7. Program is accredited through the Foundation for the Accreditation of Cellular Therapy (FACT), including Standards for Immune Effector Cells.
		8. Implements patient-centered care by including patient/family in planning and goal setting, as well as

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		managing symptoms, with the goal of improving quality of life for both the patient and the family.
		9. Commits to standard practices and monitoring for safe administration of chemotherapy.
	Commitment to measuring and improving quality of cancer care	10. Commits to system-wide monitoring and reporting of CAR-T patients through the CIBMTR registry, and to report requested quality measures to BCBSA to support designation evaluation.
		11. Incorporates measurement results into feedback and improvement of the CAR-T system of care.
Utility	Focuses on patient experience and patient engagement in shared decision making	12. Engages patient (family) in shared decision making process for goal setting and treatment planning that provides information on realistic expectations and impacts of treatment options, through use of appropriate tools, so that care delivers utility to the patient.
		13. Participates in a standardized Patient Satisfaction and Experience Survey to evaluate and improve care delivery.
Local Blue Plan Quality Criteria (if applicable)	An individual Blue Plan, at its own independent discretion, may establish and apply local business requirements as additional Selection Criteria for eligibility in a Blue Distinction Centers program, for facilities located within its Service Area.	

¹ Local Blue Plan Quality Criteria may consist of additional quality criteria beyond the national criteria, at the discretion of the local Blue Plan.

Business Criteria

Blue Distinction Centers for Cellular Immunotherapy – CAR-T Therapy	
Business Criteria Category	Selection Criteria
Facility Participation	All facilities are required to participate in the local Blue Plan's BlueCard Preferred Provider Organization (PPO) Network.
Physician Specialists Participation	All physician specialists (identified in the Provider Survey as those who perform CAR-T procedures at that facility) are required to participate in the local Blue Plan's BlueCard PPO Network ² .
Blue Brands Criteria	Provider and its corporate family meet BCBSA criteria for avoiding conflicts with BCBSA logos and trademarks.
Local Blue Plan Business Criteria³ <i>(if applicable)</i>	An individual Blue Plan, at its own independent discretion, may establish and apply local business requirements as additional Selection Criteria for eligibility in a Blue Distinction Centers program, for facilities located within its Service Area.

Value Criteria

In addition to meeting quality and business criteria, each facility is required to have a payment model for CAR-T specialty pharmacy products with their local Blue Plan that meets the Value Criteria, which includes protection against mark-up over the wholesale acquisition cost (WAC). Although a BDC+ designation is not offered at this time, the initial BDC designation incorporates an expectation of cost value; a BDC+ level may be added in a future designation enhancement, once episode based cost of care may be measured and risk adjusted meaningfully.

As the program evolves for a re-designation cycle, a global episode based payment model including medical care services is anticipated to be added as an additional program requirement in the future.

² De Minimis Rule may be applied, at the local Blue Plan's discretion

³ Local Blue Plan Business Criteria may consist of additional business criteria beyond the national criteria, at the discretion of the local Blue Plan.

Blue Distinction Centers for Cellular Immunotherapy - CART-T Therapy		
Value Criteria Category	Definition	Selection Criteria
Payment Model	Payment model with local Blue Plan for CAR-T specialty pharmacy product meets the established value criteria.	<p>Establishment of a value based payment model that includes, but is not limited to, the following concepts:</p> <ol style="list-style-type: none"> 1. Arrangements for the local Blue Plan to purchase CAR-T Specialty Pharmacy Product directly from the manufacturer or through the Provider, without mark-up from the wholesale acquisition cost (WAC)*; and 2. Incorporation of at least: <ul style="list-style-type: none"> • Additional discount off of WAC; or • Acceptance of a warranty program or other outcomes based payment model from the manufacturer(s) of the CAR-T Specialty Pharmacy Product (e.g., warranty or payment adjustment for unsuccessful patient outcome); or • Another outcomes based payment model that is associated with both quality and cost outcomes that is developed and agreed by the Provider and local Blue Plan. <p>* A Provider may not be disqualified from meeting the Value Criteria if its Local Plan payment arrangement: (1) incorporates a service fee (e.g., “administrative” or “handling” fee) for Provider services associated with handling, storing, or administering the specialty pharmacy product; or (2) complies with local or state regulatory requirements regarding provider payment rates for specialty pharmacy products.</p>
Local Blue Plan Value Criteria⁴ <i>(if applicable)</i>	An individual Blue Plan, at its own independent discretion, may establish and apply local value requirements as additional Selection Criteria for eligibility in a Blue Distinction Centers program, for facilities located within its Service Area.	

⁴ Local Blue Plan Value Criteria may consist of additional value criteria beyond the national criteria, at the discretion of the local Blue Plan.