

Blue Distinction Centers for Transplants® Clinical Program Requirements for 2008/2009 Designations

To qualify as a Blue Distinction Center for Transplants (BDCT), each facility must satisfy BDCT's quality based selection criteria. BDCT's detailed Request for Information (RFI) survey examines the facility's clinical structure, processes, and outcomes for transplant services, as well as certain responses to the American Society for Blood and Marrow Transplantation (ASBMT) Standardized RFI Transplant Administrative Survey and Program Information RFI. A mid-level description of the BDCT selection criteria for BDCT's Bone Marrow/Stem Cell Transplant category appears below; for more detail, contact the BDCT Administrator at bdcadmins@bcbsa.com. Additional quality factors may impact a local BCBS company's decision to invite a facility to participate in the BDCT RFI. Successful facilities then undergo an on-site inspection by BDCT's clinical review team. The BDCT designation process is complete after the facility enters a BDCT Participation Agreement, through which it provides global pricing for transplants (includes hospital, professional, and other provider services) and agrees to follow certain administrative requirements. Once awarded, BDCT designation is contingent on each facility's ongoing compliance with BDCT selection criteria. All BDCT facilities resubmit clinical data every eighteen months and undergo on-site inspections for all new programs and every four years for designated programs.*

Bone Marrow/Stem Cell Transplant

CATEGORY	RFI	CRITERIA DESCRIPTION	Threshold	2008 Core Points
<u>FACILITY CRITERIA</u>				
STRUCTURE				
Accreditation	BDCT, ASBMT	Full Accreditation by The Joint Commission, Healthcare Facilities Accreditation Program (HFAP) or equivalent	Yes	Required
	ASBMT	Accredited by the Foundation for the Accreditation of Cellular Therapy (FACT)	Yes	Required
Physician Credentialing	ASBMT	Has a comprehensive policy including primary verification	Yes	Required
Institute for Healthcare Improvement (IHI)	BDCT	Participates in IHI's 5 Million Lives Campaign	Yes	2
Leapfrog	BDCT	Publicly reports on Leapfrog Website via Leapfrog Group Quality and Safety Hospital Survey or Plan can substitute with a local initiative	Yes	2
Center for International Blood & Marrow Transplant Research (CIBMTR®) and Stem Cell Therapeutic Outcomes Database (SCTOD)	ASBMT	Collect and report outcomes data on all allogeneic transplants, both related and unrelated, to the SCTOD	Yes	Required
	BDCT	Collect and report outcomes data on all autologous transplants to the SCTOD	Yes	2
Clinical Trial Group Affiliation	ASBMT	Participates in one or more cooperative clinical research group (i.e. NCI, CALGB, NHLB, CIBMTR, multi-center, BMTCTN, COG, ECOG, etc.)	Yes	Required
Magnet Recognition Program	BDCT	Designated a Nurse Magnet facility		Informational
Insurance Limits	ASBMT	Must meet state requirements. In absence of state requirements, facility must carry at least 1M/3M	Yes	Required

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CATEGORY	RFI	CRITERIA DESCRIPTION	Threshold	2008 Core Points
		coverage in whole or re-insurance		
Laboratory	ASBMT / BDCT	Program has a processing laboratory that meets standards developed by the Foundation for Accreditation of Cellular Therapy (FACT)	Yes	Required
	ASBMT	The laboratory(ies) is/are accredited by an accrediting agency/ies (i.e. ASHI, CAP, CLIA, AABB or Joint Commission).	Yes	Required
Blood Banking	ASBMT	Twenty-four hour, 7 day availability of blood components including cytomegalovirus (CMV) negative/irradiated components	Yes	Required
Renal Dialysis	ASBMT	Twenty-four hour, 7 day availability	Yes	Required
Diagnostic Radiology (MRI/CT Scan)	BDCT	Twenty-four hour, 7 day availability	Yes	Required
Physical Therapy/ Rehabilitation	BDCT	Pre- and post-transplant availability of rehabilitative care	Yes	Required
Ethics Committee	BDCT	Committee is available to review ethical and medical considerations concerning transplant on an as needed basis with transplant team involvement.	Yes	1
Services	BDCT	<p>Facility (or cooperative system) has an inpatient acute care hospital that includes an Emergency Room, Intensive Care services and a full range of services.</p> <p>Facility (or cooperative system) must have a dedicated inpatient oncology unit designed to meet the complex needs of bone marrow/stem cell patients and minimizes airborne microbial contamination.</p> <p>The facility (or cooperative system) must have an on-site or nearby Radiation Oncology Unit and equipment staffed by a team of board certified radiation oncologists.</p> <p>The facility (or cooperative system) must have a designated area for outpatient care that reasonably protects the patient from transmission of infectious agents and allows, as necessary, for appropriate patient isolation, and administration of intravenous fluids, medications and/or blood products.</p>	Yes	Required
Palliative Care Team or Hospice Program	BDCT	Has a clinical Palliative Care Team <u>or</u> Hospice Program available to patients either as a direct relationship with the facility or through a referral process.	Yes	Required
		Screens transplant patients for palliative care OR hospice needs initially and at appropriate intervals throughout treatment and follow-up.		Informational

PROCESS

AAMC Principles	BDCT	Accepts the Association of American Medical Colleges (AAMC) principles for all clinical trials		Informational
Hospital Consumer Assessment of Healthcare Providers and Systems	BDCT	Participates in HCAHPS survey and makes data publicly available on the Hospital Compare website for the Summer 2008 public reporting date. (adult patients only)	Yes	2
Patient Satisfaction	BDCT	Has written process and data management systems to review patient satisfaction. (pediatric patients only)	Yes	2

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PROGRAM CRITERIA				
STRUCTURE				
National Marrow Donor Program (NMDP)	ASBMT	A member of the National Marrow Donor Program (NMDP) (unrelated allogeneic transplants only)	Yes	Required
Duration	ASBMT	Must be actively performing transplants with consecutive operation.	≥ 24 months	Required
Team*	BDCT	Stable team consisting of a program director and at minimum, one additional physician. Physicians must be actively managing/performing transplant in the same/relevant transplant type (i.e. adult, pediatric, autologous, allogeneic). <ul style="list-style-type: none"> No more than 2 named program directors / interim directors within a 3 year period No more than 35% of the team members leaving the program within 2 years The physicians shall have current board certification in hematology, medical oncology, immunology, or pediatric hematology/oncology.	Yes	Required
Program Director	BDCT	Program Director has been in current position actively managing/ performing transplantation for 2 years. OR the Program Director has been at the facility for 1 year AND 2 years as an Attending physician at a similar program. Program Director must dedicate the majority of his/her time to the clinical management of transplant patients.	Yes	Required
Attending Physician	BDCT	At least one physician, IN ADDITION to the program director, at site as an attending physician actively managing/performing transplantation for 1 year, and have had 1 year transplant specific training.	Yes	Required
Clinical Transplant Coordinators	ASBMT	Must have a clinical transplant coordinator (RN or PA) who has 1 year of transplant-relevant experience and meets ASBMT guidelines.	Yes	Required
		At least 1 clinical transplant coordinator is certified by the Oncology Nursing Certification Corporation or National Marrow Donor Program	Yes	1
Data Coordinator	ASBMT	Available to program to oversee data management process	Yes	2
Anesthesiology	ASBMT	Must have 24 hour, 7 day availability. Pediatric trained anesthesiologist must be available for pediatric programs.	Yes	Required
Infectious Disease	BDCT	Must be experienced in the care of transplant patients and must have the skills and lab available to manage patient complications.	Yes	Required
Pathology	BDCT, ASBMT	Available to program with experience in GVHD (allogeneic programs only)	Yes	Required
Radiation Oncologist	FACT	Available to program with transplant experience.	Yes	Required
Collaborative Support	BDCT	A range of subspecialties must be immediately available to the program and there must be evidence of collaborative involvement. There must be pediatric specialists for pediatric programs.	Yes	Required
Social Services	BDCT, ASBMT	Adequate resources must be available are recommended to be dedicated to the program.	Yes	Required
Lodging	ASBMT	Provides arrangements for out of area transplant patients/caregivers to have access to short-stay and long term lodging.	Yes	2

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CATEGORY	RFI	CRITERIA DESCRIPTION	Threshold	2008 Core Points
Support Groups	BDCT, ASBMT	Access to support groups	Yes	Required
	BDCT	Regular scheduled local and regional support groups must be available to pre- and post-transplant patients	Yes	1
Nutritionist/Dietician	BDCT	Available to the program and participates in patient education.	Yes	Required
Pharmacy	BDCT	Oversees and is available at the location where the preparation and dispensing of preparative regimens for stem cell transplant occur.	Yes	Required
		Dedicated to transplantation and participates in patient management and education.	Yes	1
Quality Improvements	BDCT, ASBMT	Facility has formal continuous quality improvement program (CQI) in place for hematopoietic services CQI components: --Written plan clearly shows how (pre, during, and post) transplant related issues (inpatient and outpatient) are identified, addressed, and integrated into the hospital-wide QI process --Specific to hematopoietic transplant --QI audit includes results of indicator tracking, documentation of practice changes, and current QI projects --Multidisciplinary team that meets on a regular basis --Quarterly meetings with minutes --Programmatic outcomes review occurs at least annually --Transplant specific Policies and Procedures detailing all aspects of operations, Standard Operating Procedures, personnel training, adverse events and errors, and required documentation --Designated person(s) appointed to review Policies and Procedures annually	Yes to all 8 components	3
		Yes to ≤ 7 and ≥ 5 components	2	
		Yes to ≤ 4 and ≥ 1 components	1	
		Yes to 0 components	0	

Process

Facility tracks transitions of Care	BDCT	Tracks transitions of care for patients discharged from an inpatient setting to another setting using a formal method		Informational
Patient Selection Committee and Process	BDCT, ASBMT	Regularly held, multi-disciplinary meetings (with meeting minutes documented). At minimum, the committee should include the program director, attending physician, coordinators, social worker, and appropriate consultants.	Yes	Required
Patient Selection Criteria	BDCT, ASBMT	Has written patient selection criteria that are applied to all transplant patients.	Yes	Required
		Has a process for re-evaluating patient selection criteria on an annual basis.	Yes	1
Graft versus Host Disease (GVHD) Monitoring	BDCT	Has inpatient and outpatient guidelines/protocols for GVHD prophylaxis, identification and treatment (allogeneic patients only)	Yes	2
Data Management	BDCT	Adequate personnel and systems in place to collect, analyze and maintain program data related to patient demographics, treatment plan, treatment course and outcomes. Policies in place to include: <ul style="list-style-type: none"> Responsible parties, Method for data collection, System requirements and Integration of data into the QI process 	Yes	3

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CATEGORY	RFI	CRITERIA DESCRIPTION	Threshold	2008 Core Points
Outcomes				
Volume Autologous	BDCT	<i>Adult (18 years old or older)</i> Actively performing adult autologous transplants with volume meeting required threshold of ≥ 48 transplants over 2 years and ≥ 20 transplants per year	Yes	Required
		<i>Pediatric (17 years old or younger)</i> Actively performing pediatric autologous transplants with volume meeting required threshold of ≥ 16 transplants over 2 years and ≥ 6 transplants per year	Yes	Required
Volume Allogeneic	BDCT	<i>Adult (18 years old or older)</i> Actively performing adult allogeneic transplants with volume meeting required threshold of ≥ 48 transplants over 2 years and ≥ 20 transplants per year	Yes	Required
		<i>Pediatric (17 years old or younger)</i> Actively performing pediatric allogeneic transplants with volume meeting required threshold of ≥ 24 transplants over 2 years and ≥ 8 transplants per year	Yes	Required
Volume Combined Autologous/ Allogeneic Note: pediatric volume and adult volume may not be combined	BDCT	<i>Adult (18 years old or older)</i> Actively performing combined adult autologous/allogeneic transplants with volume meeting required threshold of ≥ 72 transplants over 2 years with at least ≥ 20 transplants per year being Allogeneic and ≥ 12 per year being Autologous	Yes	Required
		<i>Pediatric (17 years old or younger)</i> Actively performing combined pediatric autologous/allogeneic transplants with volume meeting required threshold of ≥ 36 transplants over 2 years with at least ≥ 16 transplants in any one year of which ≥ 2 are Autologous and ≥ 10 are Allogeneic	Yes	Required

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Survival after transplant* (see reference table)	BDCT	<p>Adults</p> <p>100 Day 100 day actuarial disease specific survival must meet the CIBMTR Special Report U.S. aggregate actuarial survival within the 95% confidence interval for 2/3 of select diagnostic categories, (auto/allo) (within 2% for documented high risk case mix in individual diagnostic categories) Or 100 day actuarial disease specific survival must meet the CIBMTR Special U.S. aggregate actuarial survival within the 95% confidence interval of overall survival if insufficient volume of patients within select diagnostic categories</p> <p>1 Year 1-year actuarial disease specific survival must meet the CIBMTR Special Report U.S. aggregate actuarial survival within the 95% confidence interval for 2/3 of select diagnostic categories, (auto/allo) (within 2% for documented high risk case mix in individual diagnostic categories) Or 1-year actuarial disease specific survival must meet the CIBMTR Special Report U.S. aggregate actuarial survival within the 95% confidence interval of overall survival if insufficient volume of patients within select diagnostic categories</p> <p>Pediatrics</p> <p>100 Day 100 day actuarial disease specific survival must meet the CIBMTR Special U.S. aggregate actuarial survival within the 95% confidence interval of overall survival</p> <p>1 Year 1-year actuarial disease specific survival must meet the CIBMTR Special Report U.S. aggregate actuarial survival within the 95% confidence interval of overall survival</p>	Yes to all specified criteria	Required
Survival during conditioning regimen	BDCT	Patients who expired after the start of conditioning therapy (myeloablative regimen) but prior to re-infusion of stem cells for autologous transplants	≤ 5%	2
		Patients who expired after the start of conditioning therapy (myeloablative regimen) but prior to re-infusion of stem cells for allogeneic transplants	≤ 5%	2
Percentage Follow-up	BDCT	Percent of patients who are over-due for follow-up one-year post-transplant.	≤ 25%	Required
Business Requirements				
Physician Contracting	BDCT	Transplant physician(s) providing care to transplant patients must have active PPO network participating provider contracts with the local Blue Cross and/or Blue Shield Plan	Yes	Required

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Reference Table

Adult Autologous Bone Marrow/Stem Cell Transplant Survival

CIBMTR Special U.S. aggregate actuarial survival of select diagnostic categories

Disease	100 Day Survival	1 Year Survival
Non-Hodgkin Lymphoma		
Follicular - All patients	95% +/- 1	86% +/- 2
Diffuse Large Cell: In remission	95% +/- 1	84% +/- 3
Diffuse Large Cell: Not in remission	91% +/- 1	67% +/- 2
Hodgkin Disease		
Complete remission	96% +/- 1	90% +/- 1
Primary induction failure, all relapsed and advanced disease	94% +/- 2	79% +/- 3
Acute Myelogenous Leukemia (AML)		
In remission	96% +/- 2	70% +/- 3
Multiple Myeloma		
≤ 18 months diagnosis to transplant	98% +/- 1	90% +/- 1
> 18 months diagnosis to transplant	97% +/- 1	87% +/- 2

Adult Allogeneic Bone Marrow/Stem Cell Transplant Survival

CIBMTR Special U.S. aggregate actuarial survival of select diagnostic categories

Disease	Matched Related		Mismatched Related and Matched and Mismatched Unrelated	
	100 Day	1 Year	100 Day	1 Year
Acute Myelogenous Leukemia (AML)				
In remission	91% +/- 1	65% +/- 3	82% +/- 2	55% +/- 2
Not in remission	75% +/- 4	38% +/- 4	68% +/- 4	31% +/- 3
Acute Lymphoblastic Leukemia (ALL)				
In remission	87% +/- 3	60% +/- 5	81% +/- 3	55% +/- 4

Adult Autologous and Allogeneic Bone Marrow/Stem Cell Transplant Survival

CIBMTR Special U.S. aggregate actuarial survival

	All Autologous Patients	All Allogeneic Patients
100 Day	96% +/- 1	81% +/- 3
1 Year	85% +/- 2	56% +/- 5

Pediatric Autologous and Allogeneic Bone Marrow/Stem Cell Transplant Survival

CIBMTR Special U.S. aggregate actuarial survival

	All Autologous Patients	All Allogeneic Patients
100 Day	95 ± 1	86 ± 1
1 Year	84 ± 3	67 ± 1

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