Autologous Hematopoietic Stem Cell Transplantation (HSCT)

Table of Content

Effective Date	1/1993
Next Review Date	3/1/2024
Coverage Policy	Surgical 08
Version	1

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Autologous hematopoietic stem cell transplantation.

Description & Definitions:

Autologous hematopoietic stem cell transplantation is when the individual's own stem cells are removed before high dose chemotherapy or radiation, frozen for storage then thawed and returned. This process is used to replace damaged or destroyed bone marrow with blood-forming stem cells from the individual's own blood after treatment.

Criteria:

Autologous Hematopoietic Stem Cell Transplantation (HSCT) is considered medically necessary for individuals with **all of the following**:

- Individual has diagnosis of **1 or more** of the following:
  - Aplastic Anemia
  - Beta Thalassemia major
  - Breast cancer
  - Heritable Bone Marrow Syndrome
  - Leukemia
  - Lymphoma
  - Myeloma
  - Paroxysmal Nocturnal Hemoglobinuria
  - Sickle Cell Disease
- Current medical therapy has failed, and the individual has failed to respond to appropriate therapeutic management
- The individual is not in an irreversible terminal state

- The transplant is likely to prolong life and restore a range of physical and social function suited to activities of daily living

Autologous hematopoietic stem cell transplantation (HSCT) is **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Childhood-onset adrenoleukodystrophy
- Chronic myelogenous leukemia
- Diamond-Blackfan anemia
- Fanconi's anemia
- Immunodeficiency disorders
- Mucopolysaccharidosis
- Myelodysplastic syndrome
- Myelofibrosis
- Paroxysmal nocturnal hemoglobinuria
- Pure red cell aplasia
- Severe aplastic anemia
- Soft tissue sarcoma or Ewing sarcoma

Coding:

Medically necessary with criteria:

Coding	Description
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2023: March
- 2022: March
- 2019: November
- 2015: February, August
- 2014: February, May, November
- 2013: February
- 2012: February
- 2011: March
- 2010: February, August
- 2009: January, October
- 2008: January, September
- 2005: May
- 2003: April
- 2002: February
- 2001: December
- 1999: December

Reviewed Dates:

- 2018: October
- 2017: November
- 2016: February, June
- 2011: February
- 2010: June
- 2006: March, April, May, June
- 2004: April, September
- 2003: February
- 2000: December
- 1998: October
- 1996: June
- 1994: September

Effective Date:

- January 1993

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2022, Aug 31). Retrieved Jan 23, 2023, from MCG: https://careweb.careguidelines.com/ed26/index.html

(2023). Retrieved Jan 23, 2023, from AIM Specialty Health: https://guidelines.aimspecialtyhealth.com/?s=Hematopoietic+&et_pb_searchform_submit=et_search_proccess&et_pb_search_cat=11%2C1%2C96&et_pb_include_posts=yes

Autologous Hematopoietic Stem Cell Transplantation for the Treatment of Systemic Sclerosis. (2022, Aug 01). Retrieved Jan 26, 2023, from Hayes, Inc: https://evidence.hayesinc.com/report/dir.hditsclerosis4337

Blank, N., Schmalzing, M., & Moinzadeh, P. (2022, Nov 22). Autologous hematopoietic stem cell transplantation improves long-term survival-data from a national registry. Retrieved Jan 27, 2023, from PubMed: https://pubmed.ncbi.nlm.nih.gov/36424638/

CFR - Code of Federal Regulations Title 21. (2022, Nov 29). Retrieved Jan 27, 2023, from Food and Drug Administration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=1271.3

Hematopoietic Cell Transplantation (HCT). (2022, Sep 28). Retrieved Jan 23, 2023, from National Comprehensive Cancer Network: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf

Hematopoietic Stem Cell Transplantation for Treatment of Multiple Sclerosis. (2022, Mar 03). Retrieved Jan 26, 2023, from Hayes, Inc: https://evidence.hayesinc.com/report/dir.hdcms4322

LCD: Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin (L39270). (2022, Sep 04). Retrieved Jan 23, 2023, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=erector+spinae&keywordType=starts&areaId=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all

NCD: Stem Cell Transplantation (Formerly 110.8.1). (2016, Jan 27). Retrieved Jan 23, 2023, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=366&ncdver=1&keyword=stem%20cell&keywordType=starts&areaId=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

PRACTICE GUIDELINES. (2023). Retrieved Jan 27, 2023, from American Society for Transplantation and Cellular Therapy: https://www.astct.org/learn/practice-guidelines

Sieff, C. (2022, Mar 09). Overview of hematopoietic stem cells. Retrieved Jan 24, 2023, from UpToDate: https://www.uptodate.com/contents/overview-of-hematopoietic-stem-cells?search=stem%20cell%20transplantation&topicRef=14598&source=see_link#H11

PHYSICIAN-PRACTITIONER - APPENDIX D, SERVICE AUTHORIZATION. (2022, Dec 02). Retrieved Jan 26, 2023, from Department of Medical Assistance Services: https://vamedicaid.dmas.virginia.gov/sites/default/files/2022-12/Physician-Practitioner%20Manual%20App%20D%20%28Updated%2012.2.22%29_Final.pdf

(2022), Retrieved February 7, 2022, CFR – Code of Federal Regulations, Title 21, Subchapter L, Part 1271 – Human Cells, Tissues, and Cellular and Tissue-Based Products, National Archives and Records Administration, (02-1-2022): https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271

(2022), Retrieved February 7, 2022, CFR – Code of Federal Regulations, Title 21, Subchapter L, Part 1271 – Human Cells, Tissues, and Cellular and Tissue-Based Products, U.S. Food & Drug Administration, (02-06-2022): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=1271.3

(2022), Retrieved February 7, 2022, Autologous Hematopoietic Stem Cell Transplantation for the Treatment of Systemic Sclerosis, Hayes, A Symplr Company, (09-2-2021): https://evidence.hayesinc.com/report/dir.hditsclerosis4337

(2022), Retrieved February 7, 2022, Hematopoietic Stem Cell Transplantation For Treatment Of Multiple Sclerosis, Hayes, A Symplr Company, (09-2-2021): https://evidence.hayesinc.com/report/dir.hdcms4322

(2022), Retrieved February 7, 2022, NCD Stem Cell Transplantation (Formerly 110.8.1) (110.23) Version 1, N11023v1, MCG Informed Care Solutions,25th Edition, (2021): https://careweb.careguidelines.com/ed25/index.html

(2022), Retrieved February 7, 2022, Transplant, Pediatric, PO-2008, MCG Informed Care Solutions,25th Edition, (2021): https://careweb.careguidelines.com/ed25/index.html

(2022), Retrieved February 7, 2022, Medical Oncology GRG, PG-ONC, MCG Informed Care Solutions,25th Edition, (2021): https://careweb.careguidelines.com/ed25/index.html

(2022), Retrieved February 7, 2022, Initial Management of Multiple Myeloma, DynaMed Plus, (2022): https://www.dynamed.com/management/initial-management-of-multiple-myeloma

(2022), Retrieved February 7, 2022, Primary Central Nervous System Lymphoma, DynaMed Plus, (2022): https://www.dynamed.com/condition/primary-central-nervous-system-lymphoma

(2022), Retrieved February 7, 2022, Diffuse Large B-cell Lymphoma, DynaMed Plus, (2022): https://www.dynamed.com/condition/diffuse-large-b-cell-lymphoma

(2022), Retrieved February 7, 2022, Determining eligibility for autologous hematopoietic cell transplantation, Holmberg et al., UpToDate, (01-2022): https://www.uptodate.com/contents/determining-eligibility-for-autologous-hematopoietic-cell-transplantation?search=autologous%20stem%20cell%20transplant&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

(2022), Retrieved February 7, 2022, Multiple myeloma: Use of autologous hematopoietic cell transplantation, Rajkumar, S, UpToDate, (11/24/2021): https://www.uptodate.com/contents/multiple-myeloma-use-of-autologous-hematopoietic-cell-transplantation?search=autologous%20stem%20cell%20transplant&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

(2022), Retrieved February 8, 2022, Hospital Manual, Service Authorization Information, Transplant Services, Appendix D, p. 12, Department of Medical Services, Virginia Medicaid, (12-8-2021): https://www.ecm.virginiamedicaid.dmas.virginia.gov/WorkplaceXT/getContent?impersonate=true&id={203DA17D-0000-CC19-9D12-F25EE1C01D00}&vsId={2D8B984D-485F-442E-AB05-DA60627E827C}&objectType=document&objectStoreName=VAPRODOS1

(2022), Retrieved February 8, 2022, AIM Clinical Appropriateness Guidelines and Cancer Treatment Pathways, AIM Specialty Health, (11-07-21): https://guidelines.aimspecialtyhealth.com/oncologic-imaging-11-07-21/?highlight=autologous+stem+cell+transplant

(2022), Retrieved February 8, 2022, Optima Health Laboratory Testing Policies, Avalon HCS, (2022): https://www.avalonhcs.com/policies-optimahealth/

(2022), Retrieved February 8, 2022, Autologous Stem Cell Transplantation, American Society of Hematology, (2022): https://www.hematology.org/searchresults#?cludoquery=autologous%20stem%20cell%20transplant&cludopage=1&cludorefurl=https%3A%2F%2Fwww.hematology.org%2Fmeetings%2Fhighlights&cludorefpt=2022%20Highlights%20of%20ASH%C2%AE%20-%20Hematology.org&cludoinputtype=standard

(2022), Retrieved February 8, 2022, Hematopoietic Cell Transplantation, National Comprehensive Cancer Network, (2022): https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=Hematopoietic%20Cell%20Transplantation&wordsMode=AllWords

(2022), Retrieved February 8, 2022, Autologous Stem Cell Transplants, American Society of Clinical Oncology, (2022): https://beta.asco.org/search?q=autologous%20stem&filters=%7B%22contentTypeGroupLabel%22:%5B%7B%22key%22:%22General%20Information%22%7D,%7B%22key%22:%22Abstracts%20%26%20Presentations%22%7D,%7B%22key%22:%22Sessions%22%7D,%7B%22key%22:%22News%22%7D,%7B%22key%22:%22Member%20Blogs%22%7D,%7B%22key%22:%22Journals%22%7D,%7B%22key%22:%22Guidelines%22%7D,%7B%22key%22:%22Funding%20Opportunities%22%7D,%7B%22key%22:%22Patient%20Resources%22%7D,%7B%22key%22:%22ASCO%20Educational%20Book%22%7D%5D%7D&groupBy=CONTENT_TYPE

(2022), Retrieved February 8, 2022, Hematopoietic stem cell transplantation: clinical use and perspectives, Barriga et al., Biological Research, (2012): DOI: 10.4067/S0716-97602012000300012

(2022), Retrieved February 8, 2022, Autologous hematopoietic stem-cell transplantation in neurological disorders: current approach and future directions, Das et al, Expert Review of Neurotherapeutics, Vol. 12, (12-2020): DOI: 10.1080/14737175.2020.

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or

medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Acute myelogenous leukemia, Amyloidosis, Aplastic Anemia, Autologous Stem Cell Transplants, Beta Thalassemia major, bone marrow, Breast cancer, Chronic lymphocytic leukemia, Chronic myelogenous leukemia, Ewing sarcoma, Germ cell tumors of the ovary, Hematopoietic Stem Cell Transplants, Heritable Bone Marrow Syndrome, Hodgkin's lymphoma, Leukemia, Lymphoma, Multiple myeloma, Multiple sclerosis, Myelodsplastic syndrome, Myeloma, Neuroblastoma, Paroxysmal Nocturnal Hemoglobinuria, PNET, POEMS syndrome, Polyneuropathy, organomegaly, endocrinopathy, M protein, and skin changes, Primitive neuroectodermal tumors, SHP Autologous Hematopoietic Stem Cell Transplantation (HSCT), SHP Surgical 08, Sickle Cell Disease, Soft tissue sarcoma, Testicular cancer, transplants