

Autologous Myoblast and Muscle Cell Injection, Medical 262

Table of Content

[Description & Definitions](#)[Criteria](#)[Document History](#)[Coding](#)[Special Notes](#)[References](#)[Keywords](#)[Effective Date](#) 8/2008[Next Review Date](#) 2/2026[Coverage Policy](#) Medical 262[Version](#) 6

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details.

Description & Definitions:

Autologous Myoblast and Muscle Cell Injection is a procedure to biopsy a muscle and cultured before injecting into to another muscle to assist with regenerating damaged tissue.

Criteria:

Autologous Myoblast and Muscle Cell Injection is considered **not medically necessary** for any indication.

Document History:

Revised Dates:

- 2020: January
- 2016: January
- 2015: March, August, September
- 2014: October
- 2013: January, March, April, May, July
- 2012: April, November
- 2010: March, April, August
- 2009: January, April

Reviewed Dates:

- 2025: February
- 2024: February
- 2023: February
- 2022: February
- 2021: February
- 2020: February
- 2018: November
- 2017: December

- 2014: April
- 2011: April
- 2010: July

Effective Date:

- August 2008

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
53899	Unlisted procedure, urinary system.

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

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Special Notes: *

- Coverage:
 - See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products:
 - Policy is applicable to Sentara Health Plan Commercial products.
- Authorization requirements:
 - Pre-certification by the Plan is required.
- Special Notes:
 - Commercial
 - 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.
 - Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

References:

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

(2024, Mar 14). Retrieved Jan 21, 2025, from MCG 28th Edition:
<https://careweb.careguidelines.com/ed28/index.html>

(2025). Retrieved Jan 21, 2025, from Hayes - a symplr company:
<https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522autologous%2520myoblast%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522source>

(2025). Retrieved Jan 21, 2025, from Virginia Department of Medical Assistance Services:
<https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=autologous%20myoblast&gsc.sort=>

(2025). Retrieved Jan 21, 2025, from Centers for Medicare and Medicaid Services:
<https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=autologous+cellular&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all>

(2025). Retrieved Jan 21, 2025, from Google - Specialty Guideline Search:
https://www.google.com/search?q=professional+recommendation+autologous+myoblast+transplantation&safe=strict&sca_esv=8cc3bf1e6fd11b7c&rlz=1C1GCEJ_enUS1093US1093&biw=1186&bih=521&sxsrf=ADLYWIL5B0JYRtpCzZNemwESQql_M_MfXQ%3A1737487478750&ei=dvSPZ66wLa2v5NoP7Z

Approved Cellular and Gene Therapy Products. (2024, Dec 20). Retrieved Jan 22, 2025, from U.S. Food and Drug Administration: <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>

NCD: Autologous Cellular Immunotherapy Treatment (110.22). (2011, Jun 30). Retrieved Jan 21, 2025, from Centers for Medicare and Medicaid Services: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=344&ncdver=1&keyword=autologous%20cellular&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>

Subchapter F - Biologics. (2025). Retrieved Jan 22, 2025, from Code of Federal Regulations:
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F>

Young, M., & Dijkstra, P. (2024, Dec 19). Biologic therapies for tendon and muscle injury. Retrieved Jan 21, 2025, from UpToDate: https://www.uptodate.com/contents/biologic-therapies-for-tendon-and-muscle-injury?search=Autologous%20myoblast%20injection&source=search_result&selectedTitle=1%7E150&usage_type=default&display_rank=1#H2827233597

Keywords:

SHP Autologous Myoblast and Muscle Cell Injection, SHP Medical 262, incontinence, stress urinary incontinence, fecal incontinence, bowel incontinence, oral incontinence, autologous myoblast transplantation