

Autologous Myoblast and Muscle Cell Injection, Medical 262

Table of Content

Purpose

Description & Definitions

<u>Criteria</u>

Coding

Document History

References

Special Notes

Keywords

Effective Date 8/2008

Next Review Date 2/2025

Coverage Policy Medical 262

<u>Version</u> 5

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

Purpose:

This policy addresses the medical necessity of - Autologous Myoblast and Muscle Cell Injection

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.

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.

Medical 262 Page 1 of 3

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:

- 2024: February
- 2023: February
- 2022: February
- 2021: February
- 2020: February
- 2018: November
- 2016. November
- 2017: December
- 2014: April
- 2011: April
- 2010: July

Effective Date:

August 2008

References:

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

(2023, Sep 21). Retrieved Feb 13, 2024, from MCG: https://careweb.careguidelines.com/ed27/index.html

(2024). Retrieved Feb 13, 2024, from National Comprehensive Cancer Network: https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=muscle-derived%20cells

(2024). Retrieved Feb 13, 2024, from Department of Medical Assistance Services - MES Public Portal: <a href="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=Cellular%20therapies&gsc

(2024). Retrieved Feb 13, 2024, from Centers for Medicare and Medicaid Services: <a href="https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=cell%20therapy&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance

(2024). Retrieved Feb 13, 2024, from Hayes - a symplr company: <a href="https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Autologous%2520cell%2520therapy%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%25

(2024). Retrieved Feb 13, 2024, from Google - Specialty Guideline Search: https://www.google.com/search?q=Professional+recommendations+for+Autologous+muscle-

Medical 262 Page 2 of 3

derived+cells&safe=strict&sca_esv=40ad471a4e6b196f&rlz=1C1GCEJ_enUS1093US1093&sxsrf=ACQVn09IM-MWpzvn6k9SuiGKxinKK9_fPw%3A1707848924728&ei=3LTLZfqBLKvi5NoPz7CNwA4&ved=0ahUKE

Cellular & Gene Therapy Products. (2023, Mar 20). Retrieved Feb 13, 2024, from U.S. Food and Drug Administration: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products

NCD: Cellular Therapy (30.8). (N.D.). Retrieved Feb 13, 2024, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-

<u>database/view/ncd.aspx?ncdid=6&ncdver=1&keyword=cell%20therapy&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1</u>

Young, M., & Dijkstra, P. (2023, Jul 24). Biologic therapies for tendon and muscle injury. Retrieved Feb 13, 2024, from UpToDate: <a href="https://www.uptodate.com/contents/biologic-therapies-for-tendon-and-muscle-injury?search=4.%09Autologous%20muscle-injury?search=4.%09Autologous%20muscle-injury?search=4.%09Autologous%20muscle-injury.

derived%20cells&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H113398894

Special Notes: *

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.

Keywords:

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

Medical 262 Page 3 of 3