

Autologous Myoblast and Muscle Cell Injection

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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.

Document History:

Revised Dates:

- 2020: January
- 2016: January

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

Reviewed Dates:

- 2023: February
- 2022: February
- 2021: February
- 2020: February
- 2018: 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).

(2022). Retrieved Dec 09, 2022, from Hayes, Inc:

<https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522myoblast%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%2522B%2522page%2522:0,%2522size%2522:50%2522,%2522type%2522:%2522all%2522,%2522sources%2522:%2522B%2522>

(2022). Retrieved Dec 09, 2022, from Centers for Medicare and Medicaid Services: [https://www.cms.gov/medicare-coverage-database/search-](https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=muscle%20cell&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance)

[results.aspx?keyword=muscle%20cell&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance](https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=muscle%20cell&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance)

(2022). Retrieved Dec 09, 2022, from AIM Specialty Health:

https://guidelines.aimspecialtyhealth.com/?s=muscle+cell+injection&et_pb_searchform_submit=et_search_process&et_pb_search_cat=11%2C1%2C96&et_pb_include_posts=yes

(2022). Retrieved Dec 09, 2022, from National Comprehensive Cancer Network: [https://www.nccn.org/search-](https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=muscle%20cell%20injection&wordsMode=AllWords)

[result?indexCatalogue=nccn-search-index&searchQuery=muscle%20cell%20injection&wordsMode=AllWords](https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=muscle%20cell%20injection&wordsMode=AllWords)

(2022, Aug 31). Retrieved Dec 09, 2022, from MCG: <https://careweb.careguidelines.com/ed26/index.html>

(2022). Retrieved Dec 12, 2022, from Google, Inc:

https://www.google.com/search?q=autologus+myoblast+and+muscle+cell+injections+professional+recommendation&safe=strict&rlz=1C1GCEA_enUS982US982&sxsrf=ALiCzsZUo4bu49Plz-UJlt8mJdbowgK-xw%3A1670853157285&ei=JTKXY7D-ELqKp8kPoJ-HqAo&ved=0ahUKEwjwpKWHnfT7AhU6xSk

Boyer, O., Bridous, V., Giverne, C., Bission, A., Koning, E., & Leroi, A. (2018, Mar). Autologous Myoblasts for the Treatment of Fecal Incontinence. Retrieved Dec 12, 2022, from PubMed:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5805121/>

Colucci, W. (2022, Jun 29). Investigational therapies for management of heart failure. Retrieved Dec 09, 2022, from UpToDate: https://www.uptodate.com/contents/investigational-therapies-for-management-of-heart-failure?search=myoblast%20injection&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

Important Patient and Consumer Information About Regenerative Medicine Therapies. (2021, Jul 09). Retrieved Dec 12, 2022, from Food and Drug Administration: <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies>

Special Notes: *

This medical policy expresses Sentara Health Plan's determination of medical necessity of services, and they are based upon a review of currently available clinical information. 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.

Keywords:

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