CODING GUIDE

acellular tissue engineered vessel-tyod Symvess®

INTRODUCTION

Symvess® is an FDA approved[1] bioengineered, implantable blood vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible.

This guide provides information on ICD-10 codes that could apply when treating patients with Symvess. It is intended for informational purposes only and is not intended to provide an all-inclusive list of coding options. Appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with individual payers to verify codes and special billing requirements. Humacyte Global, Inc. does not make any representation or guarantee concerning reimbursement or coverage for any item or service.

HOSPITAL INPATIENT: ICD-10-PCS CODES[2]

EFFECTIVE OCTOBER 1, 2024, four new ICD-10-PCS codes are available to facilitate the accurate classification and tracking of procedures using Symvess. Should these codes be updated by CMS a new coding guide will be sent to your institution, and will also be available on **Symvess.com**.

- **X2R50WA:** Replacement of Right Upper Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10
- **X2R60WA:** Replacement of Left Upper Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10
- **X2R70WA:** Replacement of Right Lower Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10
- **X2R80WA:** Replacement of Left Lower Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10

INDICATION

SYMVESS is an acellular tissue engineered vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: GRAFT FAILURE

- Loss of SYMVESS integrity due to mid-graft rupture or anastomotic failure can result in life threatening hemorrhage.

CONTRAINDICATIONS

DO NOT use SYMVESS in patients who have a medical condition that would preclude long-term antiplatelet therapy (such as aspirin or clopidogrel) after resolution of acute injuries.

PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

SAMPLE CODING

The following codes may be relevant to Symvess procedures:

TYPE	CODE	DESCRIPTION
CPT® Code	35266	Repair blood vessel with graft other than vein; upper extremity
	35286	Repair blood vessel with graft other than vein; lower extremity
	35621	Bypass graft, with other than vein; axillary-femoral
	35623	Bypass graft, with other than vein; axillary-popliteal or -tibial
	35650	Bypass graft, with other than vein; axillary-axillary
	35654	Bypass graft, with other than vein; axillary-femoral-femoral
	35656	Bypass graft, with other than vein; femoral-popliteal
	35661	Bypass graft, with other than vein; femoral-femoral
	35666	Bypass graft, with other than vein; femoral-anterior tibial, posterior tibial, or peroneal artery
	35671	Bypass graft, with other than vein; popliteal-tibial or -peroneal artery
National Drug Code (NDC)	83564-110-01	Sealed plastic thermoformed tray
	83564-110-00	Non-sterile carton

ADDITIONAL RESOURCES

CMS Resources: 2025 ICD-10 Procedure Coding System (ICD-10-PCS) Files

Symvess Website: www.symvess.com

Contact Information for Support: For further assistance, contact Humacyte's support team at +1 833-591-0081.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS & PRECAUTIONS

- **Graft Rupture:** Vascular graft rupture has occurred in patients treated with SYMVESS. Advise patients that arterial bleeding can be life-threatening and to seek emergent medical evaluation for any signs or symptoms of graft rupture such as bleeding, pain and swelling in the extremity, or signs of extremity ischemia. Follow appropriate procedures for handling and administering SYMVESS.
- **Anastomotic Failure:** Anastomotic failure has occurred in patients treated with SYMVESS. In clinical studies of SYMVESS, anastomotic failure occurred within the first 36 days post-implantation. Monitor patients for signs of anastomotic failure such as pain and swelling at the surgical site, decreasing hemoglobin or other signs and symptoms of bleeding. Advise patients to seek urgent medical evaluation if they have any signs or symptoms that may be indicative of anastomotic failure such as bleeding, swelling or worsening pain at the surgical site or changes in color of overlying skin. Follow appropriate procedures for handling and administering SYMVESS.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS & PRECAUTIONS (CONT'D)

- **Thrombosis:** Thrombosis has occurred in patients treated with SYMVESS. In clinical trials of SYMVESS, patients received antiplatelet therapy following implantation of SYMVESS to reduce the risk of thrombosis. The risk of thrombosis may increase in patients who discontinue antiplatelet therapy. Anti-platelet therapy is recommended following treatment with SYMVESS.
- **Transmission of Infectious Diseases:** SYMVESS is manufactured using cells and reagents that may transmit infectious diseases or infectious agents. The cells used in the manufacture of SYMVESS are derived from a donor who met the donor eligibility requirements for transmissible infectious diseases. Animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use, but this does not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. No transmissible agent infections have been reported during clinical testing.

ADVERSE REACTIONS

The most common adverse reactions (≥3%) were thrombosis, fever, pain, anastomotic stenosis, rupture or anastomotic failure, and infection.

USE IN SPECIFIC POPULATIONS

Pediatric Use: The safety and effectiveness of SYMVESS in pediatric patients (0 to 17 years old) have not been established.

Geriatric Use: Two patients out of the 54 Extremity Group implanted with SYMVESS as a conduit in Study 1 were aged ≥65 years. The number of patients aged ≥65 years was not sufficient to determine whether they responded differently than younger patients to SYMVESS.

DISCLAIMER

Health economic, coding, and reimbursement information provided by Humacyte Global, Inc., is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Humacyte encourages providers to submit accurate and appropriate claims for services. It is the provider's responsibility to determine medical necessity, the proper site for delivery of any product(s), and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently.

Humacyte recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters. Humacyte does not promote the use of its products outside their FDA-approved label. The information included herein is current as of July 2024 but is subject to change without notice.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

REFERENCES: 1. Food & Drug Administration. (2024). December 19, 2024 Approval Letter - *Symvess*. Available at: https://www.fda.gov/media/184644/download. **2.** ICD-10-PCS = International Classification of Diseases, 10th Revision, Procedure Coding System.

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