

PATIENT REIMBURSEMENT GUIDE FOR VALIANT-NAVION™ THORACIC STENT GRAFT SYSTEM

SAFE-N LIMITED WARRANTY

As a patient with the Valiant Navion™ Thoracic Stent Graft System, which was used to repair your aorta, we understand you may have questions about expenses surrounding your care and treatment as a result of the Valiant Navion recall. A “recall” means that the manufacturer has asked physicians to stop using the device with new patients; it does not mean that patients have been asked to have the device removed.

As you may be aware from previous communication, on February 17, 2021, Medtronic instructed physicians to immediately stop using of the Valiant Navion device in new patients because Medtronic discovered that some patients with the device developed a leak between the stent graft and the aorta. These leaks are generally treatable and can usually be detected with Computed Tomography (“CT”) imaging. The earlier a leak is detected, the sooner it may be treated. If left untreated, leaks can potentially lead to internal bleeding. For this reason, regular imaging is an important part of follow-up for all patients implanted with a Medtronic Valiant Navion Thoracic Stent Graft.

Medtronic has developed a program to provide assistance to physicians and their patients in light of the recall. The SAFE-N (Safety Assessment for Everyone-Navion) Program has several components, including imaging and data collection, physician resources, and patient support. Medtronic is committed to working with physicians and their patients to reduce financial barriers to recommended follow-up by helping to address any unreimbursed recall-related medical expenses. Under this program, you may be eligible for reimbursement of out-of-pocket medical and incidental expenses for additional imaging and medical treatment that is directly related to the Valiant Navion recall. Medtronic is offering a Limited Warranty to provide this support. Requests for reimbursement will be processed by Syntactx/NAMSA, a third-party vendor retained by Medtronic for this purpose.

IMPORTANT

Out-of-pocket expenses related to additional imaging and medical treatment associated directly with the Valiant Navion recall are eligible for reimbursement.

DO NOT DELAY IMAGING OR TREATMENT

TO SEEK REIMBURSEMENT FOR TREATMENT

- **Have your physician or other providers submit your medical bills to insurance as usual.**
- **Contact the helpline if there are expenses that remain your responsibility.**

**U.S. SAFE-N
REIMBURSEMENT HELPLINE:**

1-833-256-2308

WHAT EXPENSES MAY BE ELIGIBLE FOR REIMBURSEMENT UNDER THE SAFE-N LIMITED WARRANTY PROGRAM?

Medtronic has contacted your physician to update an earlier recommendation for annual imaging. Medtronic now recommends that you seek routine CT imaging with contrast by your surgeon or doctor every 6 months instead of annually – or as frequently as your physician deems appropriate in his or her medical judgment. Of course, your doctor may have individualized patient recommendations about whether or when you need imaging, or what type of imaging, and Medtronic defers to your doctor in those considerations. Please contact your doctor to speak about what this new recommendation may mean for you and your ongoing care.

Each patient's imaging and medical treatment may be different based on treatment recommendations from their medical providers and other factors. Generally, out-of-pocket expenses for treatment related to the Valiant Navion recall may be reimbursed if (1) they are unreimbursed by insurance due to co-pays, coinsurance, or deductibles; (2) coverage has been denied by applicable insurance; or (3) the patient is uninsured. Where these criteria are met, reimbursement may be available for:

- Additional physician visits*
- Additional CT/MR imaging with or without contrast*
- Additional Chest X-rays*
- Procedures to reinforce the Navion graft
- Corrective surgery
- Hospital and anesthesiology services
- Inpatient hospital or rehab expenses related to reintervention
- Outpatient clinical expenses related to additional imaging and medical treatment
- Reasonable expenses related to additional imaging and medical treatment (e.g., parking, meals, hotel, time off work, and other reasonable travel expenses)
- Additional limitations may apply; reimbursements are subject to review and approval

* Lifelong, regular follow-up, including at least annual follow-up is part of routine care for Navion patients. The SAFE-N Limited Warranty Program covers updated recommendations for additional follow up and imaging every 6 months or as frequently as deemed appropriate by your physician's medical judgment.

REQUESTING REIMBURSEMENT FOR OUT-OF-POCKET EXPENSES RELATED TO IMAGING AND TREATMENT

IMMEDIATE ACTIONS

Submit Expenses to Insurance

Expenses related to your medical care and treatment should be covered by **your health insurance**.

Please have your physician and other providers submit all imaging and medical treatment expenses related to the Valiant Navion recall to your health insurance, as you would for any other medical expense. This includes insurance provided through your current or former employer; your spouse's insurance; Medicare or Medicaid or TRICARE, if applicable. Retain all Explanation of Benefit statements (EOB statements) relating to your additional imaging and medical treatment, as well as other invoices from your providers. EOB submission will be required for processing reimbursement claims.

NEXT STEPS

Contact Syntactx for More Information

If – **after you have requested reimbursement from your health insurance** – you still have eligible out-of-pocket expenses that are not covered, contact Syntactx at 1-833-256-2308 or email SAFE-N-Reimburse@syntactx.com to request information or to complete an intake form. You may also visit NavionSafety.syntactx.com for more information.

Syntactx is a confidential, third-party medical services company supporting patients and caregivers seeking assistance in processing requests for reimbursement of out-of-pocket medical and incidental expenses related to the Valiant Navion recall.

SUBMITTING A CLAIM THROUGH SYNTACTX

STEP 1

Schedule Your Follow Up Imaging or Care: It is important you do not delay care due to concerns about financial barriers. Please work with your healthcare providers to schedule and obtain the care they believe is appropriate based on your individual medical circumstances. Once you do, please maintain copies of any documents provided by your doctors or insurers for your Valiant Navion-related care.

Certain arrangements regarding payment may be needed before receiving care if you have a co-pay, deductible, or co-insurance, or if your insurance requires pre-approval. Medtronic has Syntactx available to help you. Please contact the U.S. SAFE-N reimbursement helpline: 1-833-256-2308 or email: SAFE-N-Reimburse@syntactx.com.

STEP 2

Submit Your Bills to Medicare or Insurance: Have your healthcare providers submit your medical expenses to your insurance as they typically would. Please maintain a copy of any Explanation of Benefits "EOB" or other documents you receive from your insurer, as well as a copy of any bills received from your providers. Note that you may receive bills from more than one healthcare provider for any imaging or reintervention.

STEP 3

Complete Claim Forms: If you have unreimbursed expenses related to your care, i.e., expenses for which you, the patient, remain responsible, please complete the necessary claim forms. To submit a reimbursement request for a claim, please retain copies of all paperwork submitted, including:

- Out-of-Pocket Medical Expense and/or Incidental Expense Reimbursement Claim Form(s).
- EOB documentation noting applicable deductibles, co-pays, co-insurance, and denied coverage.
- Where the requested incidental expenses exceed \$500, receipts and detailed documentation for all out-of-pocket expenses related to reasonable incidental expenses associated with seeking additional imaging and medical treatment.

STEP 4

Submit Your Claim Forms to Syntactx: Within 90 days of the imaging, reintervention, or treatment date, e-mail your completed warranty claim form to:

SAFE-N-Reimburse@syntactx.com

Mailing and facsimile are also available at:

**Syntactx
RE: SAFE-N Project
4 World Trade Center
150 Greenwich Street, 44th Floor
New York, New York, 10007**

Fax: 1 (800) 342-1401

After reviewing your submitted reimbursement form, Syntactx will send you an email message updating you on your reimbursement status. Please expect between 45-60 days to verify and process payment requests once all required forms have been submitted.

Please note that medical expense reimbursement may be paid to either the patient or facility depending on individual payment circumstances:

	Payment to Patient	Payment to Facility
Patient insured , procedure allowed, patient has paid copay	X	N/A
Patient insured , procedure allowed, patient has unpaid copay	N/A	X
Patient insured , procedure allowed, patient has no unreimbursed expenses (e.g., full coverage or secondary insurance)	N/A	N/A
Patient insured , procedure denied	N/A	X
Patient uninsured	N/A	X

ADDITIONAL QUESTIONS

Individuals with questions about this process or needing assistance are encouraged to contact:

U.S. SAFE-N reimbursement helpline: 1-833-256-2308

Email: SAFE-N-Reimburse@syntactx.com

You may also visit NavionSafety.syntactx.com

FOR MORE INFORMATION

Contact your health insurance provider for questions about coverage for your imaging and treatment.

This SAFE-N Limited Warranty is limited to its express terms and does not constitute a representation, judgment, admission, or assumption of liability by Medtronic with respect to imaging, reintervention, and/or utilized thoracic stent graft systems. No action taken by Medtronic in connection with the Voluntary Product Recall, including this SAFE-N Limited Warranty, shall be construed as an admission of any fault or liability whatsoever to the patient, doctor, health care professional, or to any third party. Medtronic makes no representation with respect to any potential impact of reimbursements on a patient's eligibility to participate in a Health Savings Account or other tax-favored health plan; please consult with a tax advisor as necessary. All rights reserved.