

PATIENT REIMBURSEMENT GUIDE FOR VALIANT-NAVION™ THORACIC STENT GRAFT SYSTEM 病人報銷指引

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.

作為曾經植入“美敦力” 范倫特納威昂胸主動脈支架的患者，我們理解由於“美敦力” 范倫特納威昂胸主動脈支架召回，您可能會對有關您的護理和治療的費用有疑問。「召回」是代表製造商通知醫師停止讓新病患使用此醫材，不代表要求病患移除體內的醫材。

As you may be aware from previous communication from your physician, on February 17, 2021, Medtronic instructed physicians to immediately stop using 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.

如同您從醫師處獲得之訊息，美敦力已於 2021 年 2 月 17 日宣布通知醫師立即停止讓**新病患**使用“美敦力” 范倫特納威昂胸主動脈支架，因為公司發現部分使用此醫材病患的主動脈覆膜支架和主動脈之間發生滲漏。這些滲漏通常可以被治療，且可以使用電腦斷層掃描（Computed Tomography, CT）進行偵測。越早偵測到滲漏，就能越快獲得治療。若未治療，則滲漏可能會造成內出血，基於此原因，定期電腦斷層掃描是所有植入“美敦力” 范倫特納威昂胸主動脈支架之病患，進行後續追蹤時非常重要的部分。

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 (“Syntactx”), a third-party vendor retained by Medtronic for this purpose.

因此，針對召回行動，美敦力制定了一項計劃以支援醫生及其患者。SAFE-N（全民安全評估-Navion）計劃有幾個組成部分，包括成像和數據收集、醫生資源和患者支援。美敦力致力於與醫生及其患者合作，協助解決任何未報銷的召回相關醫療費用。根據此計劃，您可能有資格獲得與“美敦力” 范倫特納威昂胸主動脈支架召回直接相關的額外成像*和醫療的自付費用的報銷。美敦力提供有限保證以提供此支援。報銷申請將由美敦力為此目的聘請的第三方供應商 Syntactx/NAMSA (“Syntactx”)處理。

IMPORTANT 重要事項

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

與"范倫特納威昂胸主動脈支架"召回直接相關的額外成像*和醫療相關的自付費用有資格獲得報銷。

DO NOT DELAY IMAGING OR TREATMENT

切勿延遲影像學檢查
治療

TO SEEK REIMBURSEMENT FOR TREATMENT

費用報銷申請

- Have your physician or other providers submit your medical bills to insurance as usual.
- 讓您的醫生或其他提供者像往常一樣將您的醫療帳單提交給保險。Contact the helpline if there are expenses that remain your responsibility.

如有剩餘的自付費用，請聯繫熱線
Hong Kong and Macau SAFE-N
REIMBURSEMENT HELPLINE:

SAFE-N 服務熱線

Hong Kong 香港: 800-969-726 及
Macau 澳門: +853 6262-1359

WHAT EXPENSES MAY BE ELIGIBLE FOR REIMBURSEMENT UNDER THE SAFE-N PROGRAM? 根據 SAFE-N 計劃，哪些費用可能有資格獲得報銷？

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.

美敦力已聯繫您的醫生，以更新之前的年度成像檢查建議。美敦力現在建議您**每 6 個月**或者您的醫生認為適當的醫療判斷的頻率由外科醫生或醫生進行常規電腦斷層掃描，而不是每年一次。您的醫生可能會對您是否或何時需要成像或哪種類型的成像有個人化的患者建議，美敦力在這些考慮方面尊重您的醫生專業意見。請聯繫您的醫生，談談這項新建議以及術後追蹤和護理。

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; (3) the patient is uninsured or (4) the patient refuses to claim his/her own purchased insurance.

Where these criteria are met, reimbursement may be available for:

根據醫療服務提供者的治療建議和其他因素，每位患者的成像和醫療治療可能會有所不同。一般來說，如果（1）由於共同支付，共同保險或免賠額而未被保險報銷；（2）被適用的保險拒絕承保的；（3）患者沒有保險，或（4）患者拒絕從自費保險報銷 與范倫特納威昂胸主動脈支架召回相關的治療自付費用可以報銷。

- Additional physician visits*
額外的醫生就診
- Additional CT/MR imaging with or without contrast*
附加 CT/MR 成像，帶或不帶造影劑*
- Additional Chest X-rays*
額外胸腔 X 光檢查
- Procedures to reinforce the Navion graft
加強范倫特納威昂胸主動脈支架的手術
- Corrective surgery
矯正手術
- Hospital and anesthesiology services
住院和麻醉服務
- Inpatient hospital or rehab expenses related to reintervention
與再干預相關的住院或康復費用
- Outpatient clinical expenses related to additional imaging and medical treatment
與額外影像學和醫療相關的門診費用
- Reasonable expenses related to additional imaging and medical treatment (e.g., parking, meals, hotel, time off work, and other reasonable travel expenses)
與額外成像和醫療相關的合理費用（例如，停車、膳食、酒店、休假和其他合理的差旅費用）
- Additional limitations may apply; reimbursements are subject to review and approval
可能適用其他限制;報銷須經審查和批准

* Lifelong, regular follow-up, including at least annual follow-up is part of routine care for Navion patients. The SAFE-N 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,. Uninsured patients also may be eligible for reimbursement of unreimbursed medical expenses for routine, annual imaging.

終身定期隨訪，包括至少每年隨訪是 Navion 患者常規護理的一部分。SAFE-N 計劃涵蓋了每 6 個月或醫生的醫學判斷認為適當的頻率的額外隨訪和成像的更新建議。未投保的患者也可能有資格獲得常規年度影像學檢查的未報銷醫療費用的報銷。

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

要求報銷與影像學和治療相關的自付費用

IMMEDIATE ACTIONS 立即行動

Consider whether to submit Medical Expenses to Insurance; If you would like to claim by your own purchased insurance

如閣下選擇向自費保險公司索償;

您可考慮提交醫療費用

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; National Health Insurance, 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.

請讓您的醫生和其他醫療機構將與 Valiant Navion 召回相關的所有成像和醫療費用提交到您的健康保險中，就像您支付任何其他醫療費用一樣。這包括通過您現任或前任僱主提供的保險;您配偶的保險;國民健康保險（如適用）。保留與您的額外成像和醫療相關的所有福利說明（EOB 聲明），以及您的供應商的其他發票。處理報銷申請或將需要提交 EOB。

NEXT STEPS 後續步驟

**Contact Syntactx for More Information
聯繫 Syntactx 以獲取更多資訊**

If – **after you have requested reimbursement from your own purchased insurance or you don't want to claim your own insurance**– you have / still have eligible out-of-pocket expenses that are not covered, contact Syntactx for Hong Kong at 800-969-72 and for Macau +853 626 1359 or email SAFE-N-Reimburse@syntactx.com to request information or to complete an intake form. You may also visit NavionSafety.syntactx.com/hkg and NavionSafety.syntactx.com/mac 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.

如果您在從健康保險中申請報銷後，您有或仍然有符合條件的自付費用，但未涵蓋，請致電 800-969-726（香港）；+853 626 1359（澳門）與 Syntactx 聯繫，或發送電子郵件 SAFE-N-Reimburse@syntactx.com 以請求資訊或填寫相關表格。您也可以訪問 NavionSafety.syntactx.com/hkg 及 NavionSafety.syntactx.com/mac 瞭解更多資訊。

“Syntactx 是一家保密的第三方醫療服務公司，支援尋求幫助的患者和看護人處理與 Valiant Navion 召回相關的自付費用醫療和附帶費用報銷請求。”

SUBMITTING A CLAIM THROUGH SYNTACTX 通過 SYNTACTX 提交申請

STEP 1 步驟 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.

安排您的追蹤成像或護理：重要的是，您不要因為擔心財務障礙而延遲護理。請與您的醫療保健提供者合作，根據您的個人醫療情況安排並獲得他們認為合適的護理。請保留您的醫生或保險公司為您的 Valiant Navion 相關護理提供的任何檔的副本。

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 Hong Kong SAFE-N reimbursement helpline: 800-969-726 or Macau +853 626 1359 or email: SAFE-N-Reimburse@syntactx.com.

如果您有共同支付，免賠額或共同保險，或者如果您的保險需要預先批准，則在接受護理之前可能需要有關付款的某些安排。美敦力有 Syntactx 為您提供說明。請聯繫 SAFE-N 報銷熱線香港 SAFE-N 報銷熱線：800-969-726 或 澳門 +853 626 1359 或發送電子郵件至：SAFE-N-Reimburse@syntactx.com

STEP 2 步驟 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.

將您的帳單提交給醫療保險或保險：如同一般正常程序，您的醫療保健提供者通常會將您的醫療費用提交給您的保險。請保留您從保險公司收到的任何福利解釋"EOB"或其他文件的副本，以及從您的供應商處收到的任何帳單的副本。您可能會收到來自多個醫療保健提供者的任何成像或重新干預的帳單。

STEP 3 步驟 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:

填寫申請表格：如果您有與您的護理相關的未報銷費用，即您（患者）仍然負責的費用，請填寫必要的申請表。要提交報銷申請，請保留所有提交的文書工作的副本，包括：

- Out-of-Pocket Medical Expense and/or Incidental Expense Reimbursement Claim Form(s).
自付醫療費用和/或雜費報銷報銷表
- EOB documentation noting applicable deductibles, co-pays, co-insurance, and denied coverage. (if applied)
EOB 檔，註明適用的免賠額，共同支付，共同保險和拒絕承保。（如適用）

- 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.
如果要求的雜費超過 500 美元，則提供與尋求額外影像和醫療相關的合理雜費相關的所有自付費用的收據和詳細檔。

Uninsured Patients: Uninsured patients must also complete and sign an Uninsured Status Verification Form.

無保險患者：無保險患者還必須填寫並簽署無保險身份驗證表。

STEP 4 步驟 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:

將您的申請表提交給 Syntactx：在成像、重新干預或治療日期後的 90 天內，將填妥的保證申請表通過電子郵件發送至：

SAFE-N-Reimburse@syntactx.com

Mailing and facsimile are also available at:

或郵寄和傳真至：

**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.

在審核您提交的報銷表格後，Syntactx 將向您發送一封電子郵件，更新您的報銷狀態。提交所有必需的表格後，請預計在 45-60 天內驗證和處理付款請求。

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

請注意，醫療費用報銷可能會根據個人付款情況支付給患者或設施：

	Payment to Patient 向患者付款	Payment to Facility 向設施付款
Patient insured , procedure allowed, patient has paid copay 患者 投保 ，程序允許，患者已支付共付額	X (In case patient would like to prepay and reimburse) (如果患者想預付和報銷)	N/A 不適用
Patient insured , procedure allowed, patient has unpaid copay 患者 投保 ，程序允許，患者有未支付的共付額	N/A 不適用	X
Patient insured , procedure allowed, patient has no unreimbursed expenses (e.g., full coverage or secondary insurance) 患者 投保 ，允許手術，患者沒有未報銷的費用（例如，全保或二級保險）	N/A 不適用	N/A 不適用
Patient insured but refuse to claim their own insurance 患者 投保 但拒絕要求自己的保險	X (In case patient would like to prepay and reimburse) (如果患者想預付和報銷)	X
Patient insured , procedure denied 患者 投保 ，程序被拒絕	X (In case patient would like to prepay and reimburse) (如果患者想預付和報銷)	X
Patient uninsured 沒有 保險 的病人	X (In case patient would like to prepay and reimburse) (如果患者想預付和報銷)	X

ADDITIONAL QUESTIONS 其他問題

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

對此過程有疑問或需要幫助，請聯繫：

SAFE-N reimbursement helpline:

Hong Kong: 800-969-726 or

Macau: +853 626 1359

SAFE-N 報銷熱線：

香港：800-969-726 或

澳門：+853 626 1359

Email 電郵：

SAFE-N-Reimburse@syntactx.com

You may also visit 您也可以瀏覽

香港：NavionSafety.syntactx.com/hkg 或

澳門：NavionSafety.syntactx.com/mac

FOR MORE INFORMATION 了解更多詳細資訊

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

請聯繫您的健康保險提供者，瞭解有關您的成像和治療範圍的問題。

This SAFE-N Program 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 Program, 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.

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