Health Equity Assistance Program Information Guide
Sponsored by Medtronic & Amazon Web Services

This information is intended to answer anticipated questions around the health equity assistance program to supply GI Genius™ intelligent endoscopy module(s) in underserved areas. This is not intended to replace training or clinical details to use the system in clinical practice.

What are the program details?

This program includes the opportunity to install GI Genius™ intelligent endoscopy module funded between Medtronic and Amazon Web Services (AWS), the first FDA-authorized AI device to assist clinicians in detecting polyps during colonoscopy.

The program includes a 3-year capital agreement. This program includes a service plan, that covers the installation, in-service, and any ongoing support during the duration of the first 3-years of ownership. Any upgrades of the software algorithm will be included under the service agreement. There are no additional fees or service requirements under this agreement.

What are the terms of the agreement?

The account agrees to allow Medtronic to install and in-service GI Genius™ system(s) under the health equity assistance program.

After the term of the 3-year agreement, the account is responsible for any future upgrades or the purchase of an annual service plan to receive upgrades or technical support of the equipment. If the account no longer wishes to keep the unit(s), it may be returned to Medtronic.

What are the minimum requirements of the colonoscopy tower for the GI Genius™ module?

The facility has one of the following video processors as minimum requirements for the use of GI Genius™ system:
- Olympus CV-180 EXERA II
- Olympus CV-190 EXERA III
- Fujifilm VP-4450HD
- Pentax EPK-i7000 Video Processor
- Fujifilm VP-7000

Will GI Genius™ data be collected by Medtronic or other third parties?

The GI Genius™ module is not connected into the account network. No colonoscopy video or patient healthcare information will be shared with any parties under this agreement. Medtronic will inquire about the user experience and patients served post install at different instances over the terms of the agreement to gather general metrics of the program impact in the community. This will be performed through a physician end-user survey and be at the discretion of the end-user to complete.

What is the current clinical evidence to support the use of GI Genius™ during colonoscopy?

In a recent prospective, randomized study of 685 patients, the per patient analysis showed a 14.4% absolute increase in adenoma detection rate (ADR) using high-definition (HD) colonoscopy with the GI Genius™ module compared to HD colonoscopy alone.[1] A study looking at ADR and the risk of colorectal cancer and death reported that each 1% increase in the ADR was associated with a 3% decrease in the risk of cancer.[2]

Will GI Genius™ disrupt my current experience during colonoscopy?

The use of GI Genius™ AI-assisted colonoscopy is intended to aid the endoscopist in the detection of colorectal polyps through enhanced visualization during colonoscopy. The system uses computer-aided detection algorithms to identify polyps of various sizes, shapes, and morphologies.[3]

The system does not alter or adjust the physician techniques or replace the decision-making during live colonoscopy. The use of GI Genius™ system has been reported to increase adenoma detection rate with no significant increase in withdrawal time.[1]

How long does it take to train staff to use GI Genius™ system?

Since GI Genius™ does not adjust technique of colonoscopy, the training is minimal.

The installation of GI Genius™ system to the designated colonoscopy tower is performed by a Medtronic representative. Typically, the installation will be scheduled the same day as an in-service and scheduled procedures to have live support during the first set of cases. The training is coordinated between the schedules of the physicians using GI Genius™ and the local Medtronic representative.

How many units will be provided under this agreement?

The number of systems funded will be determined after the review of all application details. Complete the application and provide justification for the number of units requested under this program.

What are the indications and risks of GI Genius™ intelligent endoscopy module?

GI Genius™ system is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. The GI Genius™ computer-assisted detection device is limited for use with standard white-light endoscopy imaging only. This device is not intended to replace clinical decision-making. GI Genius™ system is intended to be used as an adjunct to colonoscopy procedures and is not intended to replace endoscopist assessment or histopathological sampling. GI Genius™ system does not make any elaboration or alteration of the colonoscopy video streaming, it only overlays graphical markers.

If the device is used outside of the Instructions for Use it could potentially lead to inappropriate diagnostic information being displayed to the user (e.g., to analyze images from an unintended patient population, on images acquired with incompatible imaging hardware or incompatible image acquisition parameters). Incorrect detection of lesion(s) may lead to false positive or false negative which may result in incorrect patient's management with possible adverse effects: Unnecessary treatment, unnecessary additional medical imaging and/or unnecessary additional diagnostic workup such as biopsy, complications, including incorrect diagnosis and delay in disease management. Device failure could lead to the absence of results, delay of results or incorrect results, which could likewise lead to inaccurate patient assessment. In the event of unrecoverable failure please switch off and revert to non-AI enhanced colonoscopy.

For further details of warnings and risks, please visit the **Medtronic website**.

How does the facility determine if they meet criteria for the selection process?

Use the below link to access the application.

Apply Now >>>

For any additional questions about GI Genius™ in clinical practice, please click on this link to send an email.

_____

1. Alessandro Repici, Cesare Hassan, Matteo Badalamenti, Roberta Maselli, Loredana Correale, Andrea Iannone, Franco Radaelli, et al. Efficacy of real-time computer-aided detection of colorectal neoplasia in a randomized trial. Gastroenterology. 2020; 159:512–520.e7.
2. Corley DA, Jenson CD, Marks AR JR, et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. The New England Journal of Medicine. 2014; 370: 2539–2541.
3. Cesare Hassan, Michael B Wallace, Prateek Sharma, Roberta Maselli, Vincenzo Craviotto, Marco Spadaccini, Alessandro Repici. New artificial intelligence system: first validation study versus experienced endoscopists for colorectal polyp detection. Gut; 0:1–2.2020.