



## Driving change in Crohn's disease care with predictive modeling<sup>1,2,6</sup>

### Taking on unpredictability

Crohn's disease is unpredictable with a course that can vary across patients making disease management challenging. Understanding a patient's individual risk of complications is paramount to effective treatment. When this information is revealed early in the patient's journey, disease management can become more proactive.<sup>3-6</sup>

### Empowering a personalized approach to Crohn's disease care<sup>6</sup>

CDPATH is a validated\* prognostic tool that can predict a patient's individual risk for developing serious Crohn's disease complications within the next 3 years. These include bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty).<sup>3</sup>



\* The CDPATH risk assessment tool was developed and validated by Prometheus Laboratories Inc., a partner of Takeda, and has received approval from the New York State Department of Health (NYS DoH) as a Laboratory Developed Test (LDT). Test results are provided via Prometheus Laboratories Inc. to healthcare providers.<sup>1</sup>

## Powered by a novel algorithm analyzing predictive variables<sup>3,6</sup>

CDPATH's advanced algorithm distills specific patient characteristics, serologic factors, and a genetic factor into an individual risk profile.

### Key inputs that are good predictors of accuracy for risk of developing serious complications over 3 years<sup>6</sup>

#### Patient Characteristics

- **Time from diagnosis**

Establishes eligibility for CDPATH test and provides a baseline hazard function

- **Disease location**

Can help determine the likelihood of complications occurring

#### Serologic Factors

- **ASCA IgA ELISA**

- **ASCA IgG ELISA**

- **pANCA IFA**

- **Anti-CBir1 IgG**

Measures of antibodies in the blood that may predict disease course

#### Genetic Factor

- **NOD2 SNP13 (1007fs)**

A genetic factor may identify the likelihood of developing serious CD-related complications. These include bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty)<sup>3</sup>



**CDPATH Personalized Predictive Results**

Explore [CDPATH.com](https://www.cdpath.com) for more details on model development and validation

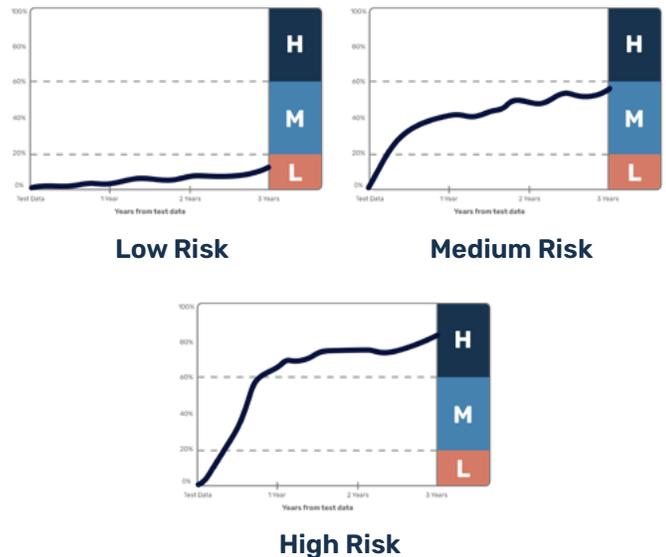
ASCA=anti-Saccharomyces cerevisiae antibodies; CBir1=anti-flagellin; ELISA=enzyme-linked immunosorbent assay; GI=gastrointestinal; IgA=immunoglobulin A; IgG=immunoglobulin G; NOD2=nucleotide-binding oligomerization domain 2; pANCA=perinuclear anti-neutrophil antibody; SNP=single-nucleotide polymorphism

## Displays complex clinical data in a single graphic<sup>3,6</sup>

CDPATH's personalized results are graphically illustrated to show whether your patient is potentially at low-, medium-, or high-risk of developing serious Crohn's disease complications<sup>6</sup> within 3 years. This unique visual approach can help your patients better comprehend their disease and their individual risk profile. Improving their understanding can help facilitate more collaboration and shared decision-making around disease management.

### Sample curves for low-, medium-, or high-risk patients<sup>6</sup>

Predicted risk of complications from Crohn's disease over 3 Years



Actual charts may vary based on each individual patient's results.

## One part of the overall picture

CDPATH results are one piece of information—a prognostic, but not a final conclusion, nor a guarantee. HCPs should not rely primarily on the results from CDPATH to make a clinical diagnosis or treatment.<sup>6</sup> CDPATH is not affiliated or linked to any Crohn's disease treatments or drugs. Results are intended to be used in combination with your clinical assessments to facilitate discussions with your patients regarding their Crohn's disease management.<sup>6</sup> These considerations may include, but are not limited to, appointment cadence, diet modifications, exercise, supplements, medications, or other approaches.<sup>7-9</sup>

## CDPATH: Empowering Better



**Better understanding** of a patient's individual disease and its risks<sup>6</sup>



**Better collaboration** and communication with patients<sup>10</sup>



**Better planning** with personalized, predictive insights<sup>3</sup>

## Offered at no cost\*

Because Takeda cares about improving patient outcomes, CDPATH is provided at no cost for eligible patients. To be considered eligible, patients must meet the following criteria:



**18 years or older**



**Diagnosed with Crohn's disease within the last 10 years**



**Have not experienced any serious disease-related complications<sup>†</sup>**



**Either on a commercial healthcare plan or are uninsured<sup>‡</sup>**

For more details on patient eligibility, visit [CDPATH.com](https://www.cdpath.com)

\* Takeda has made arrangements to cover blood draw costs at participating locations. Non-participating locations (such as an HCP's office) can be used for the blood draw. However, phlebotomy-related costs incurred at these locations would not be covered by Takeda. Takeda would still cover blood shipping to processing laboratory and CDPATH test processing. Go to [CDPATH.com](https://www.cdpath.com) to find participating locations.

<sup>†</sup> Serious Crohn's disease complications are defined as bowel strictures, internal penetrating disease, or non-perianal surgery (bowel resection or stricturoplasty).

<sup>‡</sup> Beneficiaries of any state or federal health insurance program (including, but not limited to, Medicare, Medicaid, Department of Veterans Affairs, Coast Guard, Public Health Service, or Department of Defense) are excluded from participating in this program.

## Ordering CDPATH is simple

1. Verify your patient's eligibility (left side of page 3)
2. Order a CDPATH test kit
3. Complete a CDPATH Test Requisition form; give all test materials and paperwork to your patient
4. Help your eligible patient find a participating location for the required blood draw  
Go to [CDPATH.com](https://www.cdpath.com) for participating location information
5. Discuss results with your patient and encourage their participation in disease management conversations

Participating locations for required blood draw include Quest Diagnostics Patient Service Centers, Prometheus-contracted phlebotomy sites, and mobile phlebotomy services. If a non-participating location (eg, HCP office) is preferred, Takeda will cover the cost of sample shipping and test processing, but phlebotomy charges would not be covered by Takeda.

Visit [CDPATH.com](https://www.cdpath.com) to order and personalize care for your Crohn's disease patients

CDPATH results are faxed or mailed to your office approximately 7 business days from the date the blood sample is received by the processing laboratory for testing.

Visit [CDPATH.com](https://www.cdpath.com) for additional details on patient eligibility and ordering the CDPATH test.

For more information, ask your CDPATH representatives or contact Client Services at 1-877-556-8766.

**References:** 1. Sulz MC, Burri E, Michetti P, Rogler G, Peyrin-Biroulet L, Seibold F. *Digestion*. 2020;101(suppl 1):43-47. 2. Sandborn WJ. *Gastroenterology*. 2014;147(3):702-5. 3. Siegel CA, Horton H, Siegel LS, et al. *Aliment Pharmacol Ther*. 2016;43(2):262-271 4. Columbel JF, Narula N, Peyrin-Biroulet L. *Gastroenterology*. 2017;152(2):351-361.e5. 5. Freeman HJ. *World J Gastroenterol* 2014;20(1):31-36. 6. Data on file. Takeda Pharmaceuticals. 7. Duff W, Potter G, Alcorn J, et al. *World J Gastroenterol*. 2018;24(28):3055-3070. 8. Smith MA, Smith T, Trebble TM. *Frontline Gastroenterol*. 2012;3(3):172-179. 9. Plevinsky JM, Greenley RN, Fishman LN. *Clin Exp Gastroenterol*. 2016;9:259-267. 10. Siegel CA, Lofland JH, Naim A, et al. *Dig Dis Sci*. 2015;60:2636-2645.

