

**SAMPLE PATIENT APPEAL LETTER
FOR PROMETHEUS[®] NOD2/CARD15**

(Please edit appropriately based upon your own information and medical history)

Note to Patient: If coverage was denied by your Medical Group rather than your Insurance Carrier, this letter should be addressed to the Medical Director at the Medical Group with a copy to your Insurance Carrier.

<DATE>

Red Cross Red Shield
P.O. Box 12345
Los Angeles, CA 90060

Dear Medical Appeals Reviewer:

I am writing to appeal your decision about medical coverage for the PROMETHEUS[®] NOD2/CARD15 genetic test that my gastroenterologist, Dr. Ulysses Grant at Sunnyvale Hospital in San Diego, CA ordered. Dr. Grant and I felt that this test was a medically necessary step for establishing a prognosis and treatment plan for my Crohn's disease.

PATIENT INFORMATION

I am 20 years old, and because of my diagnosis of Crohn's disease, my doctor ordered PROMETHEUS NOD2/CARD15.
(List information relevant to your symptoms and treatment)

Name: Jane Doe
Date of Birth: November 12, 1985
Insurance ID: XXX123456789
Policy Holder: Mr. John Doe
Claim #: 111111
Date of service: July 4, 2005
Original Claim: \$450.00
Date of EOB: December 31, 2005
Explanation of Benefits (EOB):

1. Out-of-network deductibles/rates applied
 2. Laboratory services available through a capitated laboratory
 3. Laboratory testing not considered medically necessary
- (List information provided on the insurance EOB)***

I would like to address these coverage issues hoping that you will reconsider your decision given the new information listed below.

TEST DESCRIPTION

PROMETHEUS NOD2/CARD15 is a genetic panel designed to detect three primary mutations associated with the down-regulation of the body's immune response to chronic inflammation in Crohn's disease. Detection of one or more of these mutations suggests likelihood for an earlier age of onset, small bowel structuring, and an elevated association with fibrostenosing disease associated with Crohn's disease. The utility of this panel is to help physicians establish a prognosis which may guide therapeutic decisions for Crohn's patients.

PROMETHEUS NOD2/CARD15 is offered only at Prometheus Laboratories Inc., a clinical reference laboratory in San Diego, California. Prometheus is CLIA certified and CAP accredited. All laboratory tests have been validated in accordance with the guidelines established by these and other agencies. Currently, Food and Drug Administration (FDA) approval is not required for testing performed by Prometheus

NETWORK PROVIDER SERVICES

Doctor Grant and I chose Prometheus to perform PROMETHEUS® *NOD2/CARD15* instead of alternative in-network laboratory testing because Prometheus is the only laboratory offering the genetic typing.

>AND/OR<

My in-network physician ordered the test and directed me to an in-network laboratory which does not offer PROMETHEUS *NOD2/CARD15*. I have made a good-faith attempt to follow insurance guidelines and was unaware of the referral to an out-of-network provider.

LABORATORY AND PHYSICIAN INFORMATION

For additional information about PROMETHEUS *NOD2/CARD15* contact Prometheus Laboratories Inc. at 1-888-423-5227. If you require additional medical information, please contact Dr. Grant at XXX-XXX-XXXX.

REFERENCE MATERIALS

- Abreu MT, Taylor KD, Lin YC, et al. Mutations in *NOD2* are Associated with Fibrostenosing Disease in Patients with Crohn's Disease. *Gastroenterology*. 2002;123(3):679-88.
- Lesage S, Zouali H, Cezard JP, et al. *CARD15/NOD2* Mutational analysis and genotype-phenotype correlation in 612 patients with inflammatory bowel disease. *Am J Hum Genet*. 2002;70(4):845-57.
- Ogura Y, Bonen DK, Inohara N, et al. A frameshift mutation in *NOD2* associated with susceptibility to Crohn's disease. *Nature*. 2001;411(6837):603-6.
- Hugot JP, Chamaillard M, Zouali H, et al. Association of *NOD2* leucine-rich repeat variants with susceptibility to Crohn's disease. *Nature*. 2001;422(6837):599-603.
- Judge T, Lichtenstein GR. The *NOD2* gene and Crohn's disease; another triumph for molecular genetics. *Gastroenterology*. 2002;122(3):826-8.

Please approve full coverage for PROMETHEUS *NOD2/CARD15* or at least apply in-network benefit coverage for this test.

Thank you for your prompt attention. I look forward to receiving a written response from you within two weeks.

Sincerely,

Jane Doe
1234 Main Street
Los Angeles, CA 90210
XXX-XXX-XXXX

cc: Dr. Ulysses Grant

cc: [YOUR STATE DEPARTMENT OF INSURANCE OR EQUIVALENT]