

SAMPLE LETTER OF MEDICAL NECESSITY
FOR PROMETHEUS™ Thiopurine Metabolites

(Please edit appropriately based on your patient's medical history and treatment experience.)

<DATE>

John Smith, Medical Director
Red Cross Red Shield
P.O. Box 12345
Los Angeles, CA 90060

Dear Dr. Smith:

I am writing to request full coverage or at least in-network benefit coverage for the diagnostic test PROMETHEUS™ Thiopurine Metabolites for my patient, Jane Doe. I am Ms. Doe's gastroenterologist practicing at Sunnyvale Community Hospital in San Diego, CA. I consider this test a medically necessary step in the treatment of my patient.

PATIENT INFORMATION

Patient: Jane Doe
ID: XXX123456789
Provider: Ulysses Grant, MD
Date of service: July 4, 2005

My patient has a history of inflammatory bowel disease and is taking thiopurine medication.
(List information relevant to the patient's symptoms, treatment and test results if applicable)

TEST DESCRIPTION

PROMETHEUS™ Thiopurine Metabolites testing assists physicians in optimizing ongoing dosing of thiopurine immunosuppressant therapy to reach and maintain therapeutic goal. Thiopurine metabolite testing also helps to identify drug metabolite levels that may lead to toxicity and some of the reasons for treatment failure.

PROMETHEUS™ Thiopurine Metabolites is performed 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 applicable agencies. Extensive studies have been performed. Currently, Food and Drug Administration (FDA) approval is not required for testing performed by Prometheus.

NETWORK PROVIDER SERVICES

I chose Prometheus to perform PROMETHEUS™ Thiopurine Metabolites for my patient instead of alternative in-network laboratory testing because this test is proprietary to Prometheus and because of the information provided on their comprehensive report.

>AND/OR<

There is no in-network provider in my area willing to refer the test or able to provide comparable testing.

LABORATORY AND PHYSICIAN INFORMATION

For additional information about the PROMETHEUS™ Thiopurine Metabolites test 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

- Dubinsky M, et al. Pharmacogenomics and metabolite measurement for 6-mercaptopurine therapy in inflammatory bowel disease. *Gastroenterology* 2000;118:705-713
- Cuffari C, et al. Utilization of erythrocyte 6-thioguanine metabolite levels to optimize azathioprine therapy in patients with inflammatory bowel disease. *Gut*. 2001;48: 642-46
- Seidman E, Clinical use and practical application of TPMT enzyme and 6-mercaptopurine metabolite monitoring in IBD. *Gastroenterol Disord*. 2003;3 Suppl 1:S30-8
- Dubinsky M, et al. A Cost-Effective Analysis of Alternative Disease Management Strategies in Patients with Crohn's Disease Treated with Azathioprine or 6-Mercaptopurine. *Am J Gastroenterol*. 2005;100(10):2239-2247

Please approve full coverage for PROMETHEUS™ Thiopurine Metabolites 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,

Ulysses Grant, MD
Sunnyvale Community Hospital
12345 Sunnyvale Road
San Diego, CA 92121
XXX-XXX-XXXX