

CYP2C19-clopidogrel Implementation Guide

This guide, created by experts in genomic medicine with real experience in implementing this genetic test in a clinical setting, will allow you to assess the current status of your implementation process to determine how best to configure your guide.

The steps below will allow you to choose among the information resources listed to help you complete and maintain a successful implementation of CYP2C19-clopidogrel testing.

Step 1: Gather Institutional Support for CYP2C19 Testing

With respect to clinical implementation of pharmacogenetics, gathering institutional support can be defined as follows:

1. Collecting and disseminating institution-specific data to justify implementation (e.g. formulary considerations, medication-use frequency, specialty therapeutic areas, clinician expertise, patient demographics)
2. Gathering evidence to support clinical utility of your implementation (e.g. primary literature, clinical practice guidelines, likelihood of a clinically actionable result, relevant patient outcomes associated with genotype-guided therapy)

Provided resources include an overview of the supporting evidence, clinical guidelines, relationship between the gene-drug pair, and sample data collection metrics that can be disseminated to raise stakeholder (e.g. physicians, pharmacists, laboratory specialists, informaticians, educators) and administrative support for the implementation.

- [Evidence Overview of CYP2C19-Clopidogrel Presentation](#)
IGNITE Network
- [Publication List: CYP2C19-Clopidogrel Evidence Overview](#)
IGNITE Network
- [CPIC Guideline for CYP2C19-Clopidogrel](#)
Clinical Pharmacogenetics Implementation Consortium

- [Clopidogrel Pathway Diagrams](#)
PharmGKB
- [CYP2C19 Pharmacogenetic Competency Presentation](#)
St. Jude Children's Research Hospital

Step 2: Develop CYP2C19 Genetic Test Ordering and Interpretation Process

Pharmacogenetic tests must be processed in a Clinical Laboratory Improvement Amendments (CLIA)-licensed laboratory in order for the results to be used clinically, which means that it is crucial to establish a genetic test ordering and interpretation process in conjunction with an in-house or outside laboratory.

Provided resources include a summary/listing of pharmacogenetic testing platforms, relevant genetic variants, laboratories, and guidance on the translation from genotype to phenotype.

- [Summary of CYP2C19 Platforms and Variants by Site](#)
IGNITE Pharmacogenetics Working Group
- [CYP2C19 Genotype Translation Table](#)
University of Florida Health Personalized Medicine Program
- [CYP2C19 Genotype Translation Table](#)
Icahn School of Medicine at Mount Sinai
- [Standard Operating Procedure: CYP2C19 Genotyping Utilizing the Spartan Rx System](#)
University of Pennsylvania
- [Genetic Testing Registry Listing for CYP2C19 Tests](#)
NIH National Center for Biotechnology Information
- [Human Genetic Tests Cleared or Approved by the Center for Devices and Radiological Health](#)
Food and Drug Administration
- [Handout for CYP2C19 Genotyping: Background and Methodology](#)
Cleveland Clinic

Step 3: Establish Reimbursement Source/Process for CYP2C19 Genetic Test

Obtaining reimbursement for pharmacogenetic testing often presents a challenge for stakeholders.

Provided resources include a glossary of payment and reimbursement terminology, guidance on using

and applying for current procedural terminology (CPT) coding, and insight into reimbursement challenges.

- [Map of Pharmacogenetic Test Reimbursement According to MAC](#)
IGNITE Network
- [Payment and Reimbursement Glossary](#)
IGNITE Clinical Validity, Utility, and Economics Working Group
- [Guidance on the Use of Current Procedural Terminology Coding for Molecular Pathology](#) IGNITE
Clinical Validity, Utility, and Economics Working Group
- [Process Map of CPT Code Assignment and Reimbursement](#)
IGNITE Clinical Validity, Utility, and Economics Working Group
- [CPT Code Spreadsheet](#)
IGNITE Clinical Validity, Utility, and Economics Working Group
- [CPT Codes for Pharmacogenomic Tests](#)
IGNITE Clinical Validity, Utility, and Economics Working Group
- [Clinical Laboratory Fee Schedule for 2018](#)
Centers for Medicare and Medicaid Services
- [Measuring the Cost Effectiveness of Pharmacogenomic Testing Presentation](#)
Indiana University
- [“Unifying the Evaluation and Implementation of Genomic Medicine” Conference Payer Meeting Proceedings](#)
IGNITE Network
- [Resources for Coverage and Reimbursement of Genetic Tests](#)
National Human Genome Research Institute
- [Clinical Laboratory Fee Schedule Files](#)
Centers for Medicare and Medicaid Services
- [Applying for CPT Code](#)
American Medical Association

Step 4: Integrate CYP2C19 Genetic Data into the EHR

In order to assist providers in interpreting and making clinical decisions upon pharmacogenetic test results, most established pharmacogenetic services collaborate with informaticians in order to integrate genetic test results into the electronic health record and develop/update clinical decision support (CDS).

Provided resources include CDS publications, sample laboratory reports, and CDS alerts containing interpretations of pharmacogenetic test results.

- [Publication List: CYP2C19-Clopidogrel Clinical Decision Support](#)
IGNITE Network
- [CYP2C19-Clopidogrel Best Practice Advisory Example \(Epic\)](#)
University of Florida Health Personalized Medicine Program
- [CYP2C19-Clopidogrel Best Practice Advisory Examples and Flow Chart \(Epic\)](#)
Icahn School of Medicine at Mount Sinai
- [CYP2C19-Clopidogrel Clinical Decision Support Examples with Drug-Genome Advisor](#)
Vanderbilt University
- [CYP2C19-Clopidogrel Clinical Decision Support Language](#)
Indiana University
- [CYP2C19-Clopidogrel Best Practice Advisory Example \(Epic\)](#)
Sanford
- [Clinical Decision Support Knowledge Base](#)
IGNITE and eMERGE Networks
- [Informatics Working Group Information](#)
Clinical Pharmacogenetics Implementation Consortium
- [Sample CYP2C19 Lab Reports](#)
LabCorp

Step 5: Develop Provider Education for CYP2C19 Testing

In an effort to increase provider knowledge of and comfort with pharmacogenetics and how it impacts patient care, continual education is essential and may include dissemination of: knowledge of and availability of pharmacogenetic testing, risks, benefits, and limitations of pharmacogenetic testing, interpretation and implications of the results, as well as provider training on the clinical workflow.

Provided resources include sample educational tools utilized by established pharmacogenetic programs to educate their providers on pharmacogenetic testing and results.

- [Institution-Specific CYP2C19-Clopidogrel Guidelines](#)
University of Maryland
- [Provider Education Brochure for CYP2C19-Clopidogrel](#)
University of Maryland
- [Provider Education Handout for CYP2C19-Clopidogrel](#)
Icahn School of Medicine at Mount Sinai
- [Provider Education Handout for CYP2C19-Clopidogrel](#)
Indiana University
- [Epic Template: Provider Education Letter with Antiplatelet Treatment Recommendations](#)
University of Maryland
- [Article: UF PharmaNote – CYP2C19 and Clopidogrel](#)
University of Florida Health Personalized Medicine Program
- [Article: UF PharmaNote – CYP2C19 and Clopidogrel Clinical Outcomes](#)
University of Florida Health Personalized Medicine Program
- [Treatment Recommendations: Antiplatelet Therapy Based on CYP2C19 Genotype](#)
University of Maryland
- [Clopidogrel Drug-Genome Interactions – MyDrugGenome](#)
Vanderbilt University
- [Medical Genetics Summary: Clopidogrel Therapy and CYP2C19 Genotype](#)
NIH National Center for Biotechnology Information
- [CYP2C19 Information Page](#)

Step 6: Development Patient Education for CYP2C19 Testing

In an effort to increase patient knowledge of and comfort with pharmacogenetics and how it impacts patient care, continual education is essential and may include dissemination of: knowledge of and availability of pharmacogenetic testing, risks, benefits, and limitations of pharmacogenetic testing, interpretation and implications of the results.

Provided resources include sample educational tools utilized by established pharmacogenetic programs to educate their patients on pharmacogenetic testing and results.

- [Patient Education Brochure for CYP2C19-Clopidogrel](#)
University of Florida Health Personalized Medicine Program
- [Patient Education Brochure for CYP2C19-Clopidogrel](#)
Icahn School of Medicine at Mount Sinai

- [Patient Education Brochure for CYP2C19-Clopidogrel](#)
University of Maryland
- [Epic Template: Patient Education Letter for CYP2C19 Results](#)
University of Maryland
- [Patient Education Handout with Wallet Cards for CYP2C19 Results](#)
University of Maryland
- [Patient Education Handout for CYP2C19-Clopidogrel](#)
Sanford Health
- [Patient Education page: CYP2C19 and Medicines](#)
St. Jude Children's Research Hospital
- [Patient Education Page with Handouts on CYP2C19 Test Results](#)
Cincinnati Children's Hospital Medical Center
- [Patient Education page: CYP2C19-Clopidogrel Summary](#)
Mayo Clinic Center for Individualized Medicine
- [Video: CYP2C19 and Clopidogrel Response](#)
Coriell Personalized Medicine Collaborative

Step 7: Establish Workflow for Clinical Pharmacogenetics Implementation of CYP2C19 Testing

When establishing the workflow for the clinical pharmacogenetics implementation, it is important to take all of the above steps and potential challenges into consideration, which can facilitate workflow optimization and expansion of the service to include additional gene-drug pairs.

Provided resources include sample clinical workflow diagrams and treatment algorithms from established pharmacogenetics programs.

- [Publication List: Clinical Implementation of CYP2C19-Clopidogrel Testing](#)
IGNITE Network
- [Workflow Diagram of Implementing CYP2C19 Testing in Clinical Care](#)
University of Florida Health Personalized Medicine Program
- [Workflow Diagram of Implementing CYP2C19 Testing in Clinical Care](#)
University of Maryland
- [Original Management Algorithm for Dual Antiplatelet Therapy in Patients Receiving PCI \(2012\)](#)
University of North Carolina at Chapel Hill
- [Revised Management Algorithm for Dual Antiplatelet Therapy in Patients Receiving PCI \(2017\)](#)
University of North Carolina at Chapel Hill

- [Challenges Associated with Implementing Pharmacogenomics into Clinical Practice Presentation](#)
Indiana University