

CYP2D6-opioids 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 CYP2D6-opioids testing

Step 1: Gather Institutional Support for CYP2D6 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.

- [Publication List: CYP2D6-Opioids Evidence Overview](#)
IGNITE Network
- [CPIC Guideline for CYP2D6-Codeine](#)
Clinical Pharmacogenetics Implementation Consortium

- [CYP2D6-Codeine Information Page](#)
PharmGKB
- [Codeine and Morphine Pathway Diagram, Pharmacokinetics](#)
PharmGKB
- [Summary of Drug Label Information for CYP2D6-Codeine](#)
PharmGKB
- [Summary of Dutch Pharmacogenetics Working Group Recommendations for CYP2D6-Tramadol](#)
PharmGKB
- [CYP2D6-Tramadol Information Page](#)
PharmGKB
- [Tramadol Pathway Diagram, Pharmacokinetics](#)
PharmGKB
- [Summary of Drug Label Information for CYP2D6-Tramadol](#)
PharmGKB
- [CYP2D6-Hydrocodone Information Page](#)
PharmGKB
- [Summary of Dutch Pharmacogenetics Working Group Recommendations for CYP2D6-Oxycodone](#)
PharmGKB
- [CYP2D6-Oxycodone Information Page](#)
PharmGKB
- [Oxycodone and Oxymorphone Pathway Diagram, Pharmacokinetics](#)
PharmGKB
- [CYP2D6 Pharmacogenetic Competency Presentation](#)
St. Jude Children's Research Hospital

Step 2: Develop CYP2D6 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.

- [CYP2D6 Genotype Translation Table](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 Genotype Translation Tables for Codeine and Tramadol](#)
Indiana University
- [Sample Interpretation of Problematic CYP2D6 Genotypes](#)
University of Florida Health Personalized Medicine Program
- [Genetic Testing Registry Listing for CYP2D6 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
- [Introduction to CYP2D6 and CYP2D6 Testing](#)
NIH National Center for Biotechnology Information
- [Genetic Pharmacology Service Test Requisition Form](#)
Cincinnati Children's Hospital
- [The CYP2D6 VCF Translator V2.0](#)
Mount Sinai

Step 3: Establish Reimbursement Source/Process for CYP2D6 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
- [LabCorp Opioid CYP2D6 Genotyping](#)
LabCorp

Step 4: Integrate CYP2D6 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: CYP2D6-Opioids Clinical Decision Support](#)
IGNITE Network
- [Example Lab Report for Poor Metabolizer](#)
University of Florida Health Personalized Medicine Program

- [Example Lab Report for Intermediate Metabolizer](#)
University of Florida Health Personalized Medicine Program
- [Example Lab Report for Extensive \(Normal\) Metabolizer](#)
University of Florida Health Personalized Medicine Program
- [Example Lab Report for Poor Metabolizer – Codeine](#)
Indiana University
- [Example Lab Report for Intermediate Metabolizer – Codeine](#)
Indiana University
- [Example Lab Report for Extensive \(Normal\) Metabolizer – Codeine](#)
Indiana University
- [Example Lab Report for Ultra-rapid Metabolizer – Codeine](#)
Indiana University
- [CYP2D6-Codeine Best Practice Advisory \(Epic\)](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6-Codeine Clinical Decision Support Language](#)
Indiana University
- [Clinical Decision Support Knowledge Base](#)
IGNITE and eMERGE Networks
- [Informatics Working Group Information](#)
Clinical Pharmacogenetics Implementation Consortium

Step 5: Develop Provider Education for CYP2D6 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.

- [CYP2D6-Opioids Treatment Recommendation Flow Chart](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6-Codeine Treatment Recommendation Flow Chart](#)
Indiana University

- [CYP2D6-Tramadol Treatment Recommendations](#)
Indiana University
- [CYP2D6 and Opioid Conversion Information Sheet](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 PM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 IM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 NM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 UM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 NM to UM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 IM with Moderate or Strong Inhibitor – Phenoconverted to PM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 NM with Moderate Inhibitor – Phenoconverted to IM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [CYP2D6 NM with Strong Inhibitor – Phenoconverted to PM – Ortho Note Template](#)
University of Florida Health Personalized Medicine Program
- [Article: UF PharmaNote – CYP2D6 and Opioids](#)
University of Florida Health Personalized Medicine Program
- [Article: UF PharmaNote – Genotype Guided Opioid Prescribing](#)
University of Florida Health Personalized Medicine Program
- [Medical Genetics Summary: Codeine Therapy and CYP2D6 Genotype](#)
NIH National Center for Biotechnology Information
- [Medical Genetics Summary: Tramadol Therapy and CYP2D6 Genotype](#)
NIH National Center for Biotechnology Information
- [CYP2D6 Information Page](#)
St. Jude Children's Research Hospital

Step 6: Develop Patient Education for CYP2D6 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.

- [Pharmacogenetic Testing Brochure](#)
Mission Health
- [Breastfeeding and Medication Safety](#)
Mission Health
- [Patient Education Page: CYP2D6 and Medicines](#)
St. Jude Children's Research Hospital
- [Patient Education Page with Handouts on CYP2D6 Test Results](#)
Cincinnati Children's Hospital
- [Patient Education Page: CYP2D6-Codeine Summary](#)
Mayo Clinic Center for Individualized Medicine
- [Patient Education Page: CYP2D6-Tramadol Summary](#)
Mayo Clinic for Individualized Medicine
- [How Your Genes Affect Your Reaction to Drugs](#)
Cleveland Clinic
- [Genetic Pharmacology Service – Frequently Asked Questions](#)
Cincinnati Children's Hospital Medical Center
- [Clinical Pharmacogenomics Service Program](#)
Boston Children's Hospital

Step 7: Establish Workflow for Clinical Pharmacogenomics Implementation of CYP2D6 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 CYP2D6-Opioids](#)
IGNITE Network