Patient Acknowledgment Form for Pharmacogenomics Services

Do not use this form for BCBS North Dakota members, North Dakota Medicaid or Medicare beneficiaries – they require payer-specific notices.
All blanks on this form are required to be filled in before starting testing.
When this form is completed with all required information, fax form to (605) 312-8964.

Signing of this form allows Sanford to bill you directly for testing indicated below if it is not paid for by your insurance.

Patient Name (Printed)	E Number	Date of Service	Place of Service

Check the test(s) below that is/are to be done:

____ CYP2C9 (CPT 81227)
____ VKORC1 (CPT 81355)
____ CYP2C19 (CPT 81225)
____ CYP2D6 (CPT 81226)
____ CYP3A5 (CPT 81231)
____ CYP2C Cluster
____ SLCO1B1 (CPT 81328)
____ TPMT (CPT 81335)
____ DPYD (CPT 81232)
____ CYP4F2 (CPT 81479)
____ IFNL3 (CPT 81283)

Dr. _____ or his/her designee has asked that I have the testing done as checked above.

I understand and agree:

- My health insurance policy has limited or no coverage for this testing.
- This limitation is not because of a decision by Sanford Health. It is because of the limits of my policy.
- The estimated charges for this testing are $199.00, regardless of how many single genes are ordered.
- To have the testing indicated done even if my insurance company will not pay for part of the test or the entire test.

By signing this acknowledgment:

- I agree to pay for the amount that is not paid for by my insurance.

Signature of patient	Insurance ID Number from Patient Insurance Card	Date

Authorized patient representative signature (where applicable)	Date

Physician or Clinic Representative (printed)	Phone Number	Date

Why is my provider ordering this testing?

We all differ in terms of how our bodies respond to drugs. In our bodies, we differ in how drugs are:

- Absorbed
- Eliminated (removed) from our bodies
- Distributed
- Metabolized (processed)

Most drugs are processed (metabolized) in our bodies by our liver. The parts of the liver that metabolize drugs are called “enzymes.” Enzymes are made from the genes in our body. We inherit different genes from our mothers and our fathers. By testing the genes for our drug metabolizing enzymes and other proteins impacting drug response, doctors can gain insight into how a patient might respond to certain commonly prescribed drugs.

The results given from any or all of the tests listed above may help Sanford providers to select and prescribe the safest drugs for our patients. These tests are part of the covered services under the Sanford Health Plan; however these services are subject to:

- Co-insurance
- Deductible requirement

For BCBS Wellmark Members

Medical Policy Summaries for CYP2C9, CYP2C19, CYP2D6, CYP4F2, IFNL3, CYP2C cluster, CYP3A5, VKORC1, SLCO1B1, TPMT and DPYD.

Genetic testing to determine cytochrome p450 2C9 (CYP2C9) and vitamin K epoxide reductase subunit C1 (VKORC1) genetic polymorphisms is considered investigational for the purpose of managing the administration and dosing of warfarin, including use in guiding initial warfarin dose to decrease time to stable INR and reduce the risk of serious bleeding.

While the evidence suggests a strong association between genetic variants and stable warfarin dose, and to a lesser extent, between genetic variants and INR and bleeding outcomes, the impact of this testing on clinical outcomes (clinical utility) is not currently established. The evidence is insufficient to inform conclusions concerning the impact of this testing on warfarin-related adverse events and hospitalizations, and the impact on quality of life. Therefore, genetic testing to determine cytochrome p450 2C9 (CYP2C9) and vitamin K epoxide reductase subunit C1 (VKORC1) genetic polymorphisms is considered investigational.

Genotyping to determine cytochrome P450 (CYP2C19, CYP2D6, CYP2C9) genetic polymorphisms to determine drug metabolizer status is considered investigational for all indications.

Current evidence regarding the use of genotyping tests for the determination of drug metabolizer status indicates that while available testing methods may accurately identify genetic variations in an individual, there is insufficient data to demonstrate that such testing, and the clinical decisions made based on the testing, results in a significant impact on health outcomes. Specifically, clinical trials have not yet adequately demonstrated that such testing results in either enhanced clinical effectiveness, or in decreased short-term or long-term serious adverse events. Therefore, this testing is considered investigational. Access BCBS Wellmark website for full policy description:

Access BCBS Wellmark website for full policy description:
https://www.wellmark.com/Provider/MedpoliciesAndAuthorizations/MedicalPolicies/policies/Pharmacogenomic_test_drug_metabolism.aspx

Wellmark of South Dakota, as well as other payers, may consider these services as experimental or not medically necessary.

This acknowledgment is to advise you of this noncoverage and that these charges will be your responsibility. The physician or clinic representative signature indicates a meeting with the patient and/or policy holder and explanation regarding noncoverage was discussed and understood by the patient and/or policy holder.

* * * While an explanation of benefits may indicate otherwise, a valid, signed waiver constitutes financial liability on behalf of the patient/policy holder.