

PHELIX Medical Necessity Intelligence

Traditional Medicare - Novitas | Phase 1 PRE-TEST | v1.5 | Novitas Fixed Standard

Patient	DOB	Sex	Provider	Specimen	Diagnosis
CARDIO DEMO1	07/01/1966	Male	Sam Smith, MD	CARDIO12341	I50.9 - Heart failure, unspecified

Novitas Fixed Medical Necessity Crosswalk

Current medication	Novitas drug-gene match	Documented ICD-10 match	Phase 1 Novitas result
Meloxicam 5 mg	YES - CYP2C9; 81227/0349U	NO - I50.9 is not in CYP2C9 Group 5	DRUG-GENE MATCH / DIAGNOSIS GATE NOT MET
Simvastatin 40 mg	YES - SLCO1B1; 81328/0349U	NO - I50.9 is not in SLCO1B1 Group 11	DRUG-GENE MATCH / DIAGNOSIS GATE NOT MET
Metoprolol 100 mg	NO - not listed in A58801 CPIC/FDA drug tables	I50.9 appears in CYP2D6 Group 4, but drug gate fails	NOT NOVITAS-QUALIFYING AS CURRENT DRUG
Fluoxetine 100 mg	NO - fluoxetine not listed; other SSRIs are listed	I50.9 appears in Group 4, but drug gate fails	NOT NOVITAS-QUALIFYING AS CURRENT DRUG
Irbesartan / Amiodarone / Apixaban / Eplerenone	No direct current Novitas drug-gene match identified in A58801	I50.9 alone does not create a drug-gene match	NOT NOVITAS-QUALIFYING AS CURRENT DRUG

Phase 1 Genetic Firewall

Actual genotype is excluded. Inherited genetics remain ASSUMED/DEFAULT NORMAL - NOT TESTED RESULTS.

Current Novitas Medical Necessity Conclusion

With the source record as provided, there is no fully qualified CURRENT drug-gene-diagnosis relationship because meloxicam and simvastatin meet the Novitas drug-gene gate but I50.9 does not meet their gene-specific ICD-10 groups. This is a documentation/coverage conclusion, not a statement that the clinical PK risks are absent.

Meloxicam 5 mg / CYP2C9 - Sections 1-4

Section 1 - Reason for PGx Testing

Provider-selectable reason	Selection/details
☐ Suspected drug-related symptoms/non-therapeutic response	
☐ Dosage modification	
☐ Medication replacement/new drug consideration	

Section 2 - Approved Drug-Gene-Diagnosis Match

Novitas drug-gene gate: YES (meloxicam-CYP2C9). Diagnosis gate: NOT MET with I50.9. Provider should add only a clinically accurate diagnosis that is actually documented and supported; do not code solely to obtain coverage.

Section 3 - Phenoconversion/TruTYPE Risk

Assumed-normal CYP2C9 - NOT TESTED; amiodarone moderate inhibition -> functional Slower than normal.

Section 4 - Published Guidance

CPIC/FDA/source: reduced CYP2C9 metabolism can increase meloxicam exposure and adverse-effect risk.

Simvastatin 40 mg / SLCO1B1 - Sections 1-4

Section 1 - Reason for PGx Testing

Provider-selectable reason	Selection/details
☐ Suspected drug-related symptoms/non-therapeutic response	
☐ Dosage modification	
☐ Medication replacement/new drug consideration	

Section 2 - Approved Drug-Gene-Diagnosis Match

Novitas drug-gene gate: YES (simvastatin-SLCO1B1). Diagnosis gate: NOT MET with I50.9. Group 11 includes hyperlipidemia/atherosclerotic and specified history codes, but none is documented in this source case.

Section 3 - Phenoconversion/TruTYPE Risk

Assumed-normal SLCO1B1 - NOT TESTED. Actual genotype remains excluded from Phase 1.

Section 4 - Published Guidance

CPIC/FDA/source: reduced OATP1B1 function or inhibition can increase simvastatin acid exposure and myopathy risk.

Medical Necessity Trigger Logic

CURRENT medication	Provider question	Novitas consequence
Amiodarone 150 mg	Is propafenone actually being considered? ☐ No ☐ Yes	If YES, propafenone becomes CONSIDERED. Novitas A58801 lists propafenone-CYP2D6, and I50.9 is in CYP2D6 Group 4; rerun full qualification.
Fluoxetine 100 mg	Is a Novitas-listed PGx-supported SSRI actually being considered? ☐ No ☐ Yes: _____	Only a provider-confirmed listed drug becomes CONSIDERED. Clinical indication must also be documented accurately.

Final Medical Necessity Summary

Current source data produce two Novitas drug-gene matches (meloxicam-CYP2C9 and simvastatin-SLCO1B1) but neither has a matching documented Novitas ICD-10 with I50.9 alone. No CURRENT medication produces a fully qualified Novitas drug-gene-diagnosis relationship. Provider confirmation of propafenone consideration would create a prospective CYP2D6 relationship requiring rerun; I50.9 is an allowed Group 4 diagnosis.

Suggested EMR / Order Note

PGx testing considered because of clinically significant medication PK/DDI risk. Novitas coverage crosswalk currently identifies meloxicam-CYP2C9 and simvastatin-SLCO1B1 drug-gene relationships, but the documented diagnosis I50.9 does not satisfy their gene-specific ICD-10 groups. Provider to document only clinically accurate additional diagnoses and any actually considered medication before claim submission.

Suggested Medication Action Plan

Pre-result only. Do not make genotype-based changes from Phase 1 assumptions. Clinical risk management remains separate from payer qualification.

Provider Attestation

Provider: Sam Smith, MD NPI: _____ Signature: _____ Date: _____