MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: MP.122.MH
Last Review Date: 08/04/2016
Effective Date: 09/01/2016

MP.122.MH – Plavix (Clopidogrel) Metabolism, Genetic Test

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers **Plavix (Clopidogrel) Metabolism Genetic Test** medically necessary for members meeting all of the following indications:
1. Clopidogrel (Plavix) being considered for treatment;
2. Test completed before treatment begins;
3. No previous genetic testing for clopidogrel (Plavix) has been done.

Limitations
Members are limited to one test per lifetime. Genotype test results are valid life-long making repeat genetic testing for clopidogrel (Plavix) metabolism of no proven value.

Genetic testing for the CYP2C19 gene is considered investigational at this time for all other indications including, but not limited to the following medications:
- Amitriptyline
- Proton pump inhibitors
- Selective serotonin reuptake inhibitors
- Warfarin

Background
Clopidogrel bisulfate (Plavix) is a widely prescribed medication to/for:
- Prevent blood clots in patients with acute coronary syndrome (ACS),
- Other cardiovascular (CV) disease-related events,
- Undergoing percutaneous coronary intervention.

CYP2C19 is one of the principal enzymes involved in the metabolism of clopidogrel (Plavix). The presence of CYP2C19*2, a gene variant, can cause poor metabolism of the drug which can lead to increased risk for adverse cardiovascular events.

Genetic testing is available to identify a patient's CYP2C19 genotype (including the presence of gene variants) which can be used in determining the therapeutic strategy for treatment with Clopidogrel (Plavix). Examples of test names are: AccuType® CP, AccuType, ™ and clopidogrel CYP2C19 genotyping.

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Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
Covered CPT Codes	
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g. drug metabolism), gene analysis, common variants (e.g. *2,*3,*4,*8,*17)
ICD-9 codes covered if selection criteria are met:	
410.00-410.92	Acute myocardial infarction
411.0-411.89	Acute and subacute forms of ischemic heart disease
413.0-413.9	Angina Pectoris
414.00-414.9	Chronic ischemic heart disease
433.00-434.91	Occlusions and stenosis of precerebral and cerebral arteries
443.89-443.9	Peripheral vascular diseases
ICD-10 codes covered if selection criteria are met:	
I20.0-I20.9	Angina Pectoris
I21.01-I21.4	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I22.0-I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I24.0-I24.9	Acute ischemic heart diseases
I25.10-I25.9	Chronic ischemic heart disease
I63.00-I63.9	Occlusions and stenosis of cerebral/precerebral arteries resulting in cerebral infarction
I65.29	Occlusion and stenosis of unspecified carotid artery
I66.01-I66.9	Occlusions and stenosis of cerebral arteries , not resulting in cerebral infarction
I73.89-I73.9	Other specified peripheral vascular diseases/ Peripheral vascular disease, unspecified

Variations

For Medicare Members in Maryland:

Medicare regulations at 42CFR410.32 (a) require in relevant part that “All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the

physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."

There is scant evidence of general clinical uptake of pharmacogenomic diagnostic testing to guide patient management, which continues to lack sufficient evidence of decision impact, despite emerging supportive technical research. Additional evidence would inform contractor determinations that certain pharmacogenomic tests are furnished appropriately under the regulation. As further described in regulations at 42CFR411.15 (k) (1) these tests would otherwise not be reasonable and necessary "for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Therefore, noting an equivocal EGAPP technology assessment in the area of adjunctive treatment of depression with selective serotonin reuptake inhibitors, Cytochrome P450 CYP2C19 and CYP2D6 allele testing will be covered only in the context of approved prospective clinical studies that demonstrate the use of the results in the management of a beneficiary's specific medical problem.

Furthermore, although the Cytochrome P450 CYP2C19 enzyme metabolizes approximately 15% of all prescribed drugs and is involved in the metabolism of several important drug classes, including, but not limited to, anti-depressants (amitriptyline), anti-epileptics (phenytoin) and proton pump inhibitors (lansoprazole), routine testing is not supported by a sufficiently robust evidence base of medical necessity. However, in the context of an FDA boxed warning for clopidogrel dosing where impaired Cytochrome P450 CYP2C19 metabolism has been reported, testing is a coverable service.

References

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