REIMBURSEMENT POLICY STATEMENT
OHIO MEDICAID

Original Issue Date	Next Annual Review	Effective Date
12/01/2018	12/01/2019	12/01/2018
Policy Name		**Policy Number**
Molecular Diagnostic Testing for Herpes Simplex Virus		PY-0449
Policy Type		
Medical	Administrative	Pharmacy	**REIMBURSEMENT**

Reimbursement Policies prepared by CSMG Co. and its affiliates (including CareSource) are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Reimbursement Policies.

In addition to this Policy, Reimbursement of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or Reimbursement of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

CSMG Co. and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

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A. SUBJECT

Molecular Diagnostic Testing for Herpes Simplex Virus

B. BACKGROUND

Molecular testing, following a diagnosis or suspected diagnosis can help guide appropriate therapy by identifying specific therapeutic targets and appropriate pharmaceutical interventions. Molecular diagnostic testing utilizes Polymerase Chain Reaction (PCR), a genetic amplification technique that only requires small quantities of DNA, for example, 0.1 mg of DNA from a single cell, to achieve DNA analysis in a shorter laboratory processing time. Knowing the gene sequence, or at minimum the borders of the target segment of DNA to be amplified, is a prerequisite to a successful PCR amplification of DNA.

Herpes Simplex Virus (HSV) type 1 (HSV-1) or type 2 (HSV-2) causes the sexually transmitted disease genital herpes. Individuals infected with HSV can be asymptomatic, have very mild symptoms or have symptoms that are mistaken for another skin condition. Herpes lesions typically appear as vesicles, small blisters, on or around the genitals, rectum or mouth. The first outbreak of herpes is often associated with a longer duration of herpetic lesions, increased viral shedding (making HSV transmission more likely) and systemic symptoms including fever, body aches, swollen lymph nodes, or headache. Genital herpes may cause painful genital ulcers that can be severe and persistent in persons with suppressed immune systems, such as HIV-infected persons. Both HSV-1 and HSV-2 can also cause rare but serious complications such as aseptic meningitis (inflammation of the linings of the brain). Development of extragenital lesions (e.g. buttocks, groin, thigh, finger, or eye) may occur during the course of infection.

The preferred HSV tests for patients with active genital ulcers are detection of HSV DNA by nucleic acid amplification tests such as polymerase chain reaction (PCR), or isolation by viral culture. HSV culture requires collection of a sample from the lesion and, once viral growth is seen, specific cell staining to differentiate between HSV-1 and HSV-2. However, culture sensitivity is low, especially for recurrent lesions, and declines as lesions heal. PCR is more sensitive, allows for more rapid and accurate results, and is increasingly being used. Because viral shedding is intermittent, failure to detect HSV by culture or PCR does not indicate an absence of HSV infection. For the symptomatic patient, testing with both virologic and serologic assays can determine whether it is a new infection or a newly-recognized old infection. A primary infection would be supported by a positive virologic test and a negative serologic test, while the diagnosis of recurrent disease would be supported by positive virologic and serologic test results.

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Although CLIA requires that waived tests must be simple and have a low risk for erroneous results, this does not mean that waived tests are completely error-proof. CareSource may periodically require review of a provider's office testing policies and procedures when performing CLIA-waived tests.

C. DEFINITIONS

- **Polymerase Chain Reaction (PCR)** - a genetic amplification technique also known as a Nucleic Acid Amplification Test (NAAT)
- **Medically Necessary**- Health care services or supplies needed to diagnosis or treat an illness, injury, condition, disease or its symptoms and that meet the accepted standards of medicine.

D. POLICY

I. No Prior Authorization is required for the Molecular Diagnostic Testing by PCR addressed in this policy.

II. CareSource considers Molecular Diagnostic Testing by PCR for Herpes Simplex Virus medically necessary when submitted with any combination of the CPT and diagnosis codes listed in the Conditions of Coverage in this policy

III. CareSource does not consider Molecular Diagnostic Testing by PCR for Herpes Simplex Virus to be medically necessary when billed with any other diagnosis code and will not provide reimbursement for those services.

IV. Conventional testing, such as serology and cultures, are viewed as low cost and should be utilized before the higher cost Molecular Diagnostic Testing by PCR.

E. CONDITIONS OF COVERAGE

CODE	DESCRIPTION
87529	Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, amplified probe technique
87530	Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, quantification
87532	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, amplified probe technique
87533	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, quantification
A60.00	Herpesviral infection of urogenital system, unspecified
A60.01	Herpesviral infection of penis
A60.02	Herpesviral infection of other male genital organs
A60.03	Herpesviral cervicitis
A60.04	Herpesviral vulvovaginitis
A60.09	Anogenital herpesviral infection, unspecified
A60.1	Herpesviral infection of perianal skin and rectum
A60.9	Anogenital herpesviral infection, unspecified
B00.0	Eczema herpeticum
B00.1	Herpesviral vesicular dermatitis
B00.2	Herpesviral gingivostomatitis and pharyngotonsillitis
B00.3	Herpesviral meningitis
B00.4	Herpesviral encephalitis
B00.50	Herpesviral ocular disease, unspecified
B00.51	Herpesviral iridocyclitis
B00.52	Herpesviral keratitis
B00.53	Herpesviral conjunctivitis
B00.59	Other herpesviral disease of eye
B00.7	Disseminated herpesviral disease
B00.81	Herpesviral hepatitis
B00.82	Herpes simplex myelitis
B00.89	Other herpesviral infection
B00.9	Herpesviral infection, unspecified
B08.21	Exanthema subitum [sixth disease] due to human herpesvirus 6
B10.01	Human herpesvirus 6 encephalitis
B10.81	Human herpesvirus 6 infection

O98.311	Other infections with a predominantly sexual mode of transmission complicating pregnancy, first trimester
O98.312	Other infections with a predominantly sexual mode of transmission complicating pregnancy, second trimester
O98.313	Other infections with a predominantly sexual mode of transmission complicating pregnancy, third trimester
O98.319	Other infections with a predominantly sexual mode of transmission complicating pregnancy, unspecified trimester
O98.32	Other infections with a predominantly sexual mode of transmission complicating childbirth
O98.33	Other infections with a predominantly sexual mode of transmission complicating the puerperium
O98.511	Other viral diseases complicating pregnancy, first trimester
O98.512	Other viral diseases complicating pregnancy, second trimester
O98.513	Other viral diseases complicating pregnancy, third trimester
O98.519	Other viral diseases complicating pregnancy, unspecified trimester
O98.52	Other viral diseases complicating childbirth
O98.53	Other viral diseases complicating the puerperium

F. RELATED POLICIES/RULES

N/A

G. REVIEW/REVISION HISTORY

	DATE	ACTION
Date Issued	12/01/2018	
Date Revised	11/7/2018	Added ICD-10 098.519 in code table, corrected next review date to reflect 12/01/2019
Date Effective		

H. REFERENCES

1. STD Facts - Genital Herpes (Detailed version). (2017, February 9). Retrieved July 10, 2018, from www.cdc.gov/std/herpes/stdfact-herpes-detailed.htm.

The Reimbursement Policy Statement detailed above has received due consideration as defined in the Reimbursement Policy Statement Policy and is approved.