Retinal Telescreening for Diabetic Retinopathy

Policy # 00026
Original Effective Date: 08/25/2003
Current Effective Date: 10/01/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider retinal telescreening with digital imaging and manual grading of images as a screening technique for the detection of diabetic retinopathy to be **eligible for coverage.****

Table PG1. American Diabetes Association Retinopathy Screening Recommendations

Patient Group	First Retinal Examination	Follow-Up
Adults with type 1 diabetes	Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 y after the onset of diabetes	Yearly
Type 2 diabetes	Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of diagnosis of diabetes	Yearly
Pregnancy in preexisting diabetes	Before pregnancy or in the first trimester	Every trimester and for 1 y postpartum as indicated by the degree of retinopathy

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers retinal telescreening for all other indications, including the monitoring and management of disease in individuals diagnosed with diabetic retinopathy to be **investigational.***

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Based on review of available data, the Company considers digital retinal imaging with automated image interpretation for the detection of diabetic retinopathy to be **investigational.***

Background/Overview

Diabetic Retinopathy

Diabetic retinopathy is the leading cause of blindness among adults aged 20 to 74 years in the United States. The major risk factors for developing diabetic retinopathy are the duration of diabetes and severity of hyperglycemia. After 20 years of disease, almost all patients with type 1 and more than 60% of patients with type 2 diabetes will have some degree of retinopathy. Other factors that contribute to the risk of retinopathy include hypertension and elevated serum lipid levels.

Diabetic retinopathy progresses, at varying rates, from asymptomatic, mild non-proliferative abnormalities to proliferative diabetic retinopathy, with new blood vessel growth on the retina and posterior surface of the vitreous. The two most serious complications for vision are diabetic macular edema and proliferative diabetic retinopathy. At its earliest stage (non-proliferative retinopathy), the retina develops microaneurysms, intraretinal hemorrhages, and focal areas of retinal ischemia. With the disruption of the blood-retinal barrier, macular retinal vessels become permeable, leading to exudation of serous fluid and lipids into the macula (macular edema). As the disease progresses, retinal blood vessels are blocked, triggering the growth of new and fragile blood vessels (proliferative retinopathy). The new blood vessels that occur in proliferative diabetic retinopathy may fibrose and contract, resulting in tractional retinal detachments with significant vision loss. Severe vision loss with proliferative retinopathy arises from vitreous hemorrhage. Moderate vision loss can also arise from macular edema (fluid accumulating in the center of the macula) during the proliferative or non-proliferative stages of the disease. Although proliferative disease is the main cause of blinding in diabetic retinopathy, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

Screening

There is potential value in screening for diabetic retinopathy because diabetic retinopathy has few visual or ocular symptoms until vision loss develops. Because treatments are primarily aimed at preventing vision loss, and retinopathy can be asymptomatic, it is important to detect disease and begin treatment early in the process. Annual dilated, indirect ophthalmoscopy coupled with biomicroscopy or 7-standard field stereoscopic 30° fundus photography, has been considered the

screening technique of choice. Because these techniques require a dedicated visit to a competent eye care professional, typically an ophthalmologist, retinopathy screening is underutilized. This underuse has resulted in the exploration of remote retinal imaging, using film or digital photography, as an alternative to direct ophthalmic examination of the retina.

Treatment

With early detection, diabetic retinopathy can be treated with modalities that can decrease the risk of severe vision loss. Tight glycemic and blood pressure control is the first line of treatment to control diabetic retinopathy, followed by laser photocoagulation for patients whose retinopathy is approaching the high-risk stage. Although laser photocoagulation is effective at slowing the progression of retinopathy and reducing visual loss, it causes collateral damage to the retina and does not restore lost vision. Focal macular edema (characterized by leakage from discrete microaneurysms on fluorescein angiography) may be treated with focal laser photocoagulation, while diffuse macular edema (characterized by generalized macular edema on fluorescein angiography) may be treated with grid laser photocoagulation. Corticosteroids may reduce vascular permeability and inhibit vascular endothelial growth factor production, but are associated with serious adverse events including cataracts and glaucoma, with damage to the optic nerve. Corticosteroids can also worsen diabetes control. Vascular endothelial growth factor inhibitors (eg, ranibizumab, bevacizumab, pegaptanib), which reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis), are also used for the treatment of diabetic macular edema and proliferative diabetic retinopathy.

Digital Photography and Transmission Systems for Retinal Imaging

A number of photographic methods have been evaluated that capture images of the retina to be interpreted by expert readers, who may or may not be located proximately to the patient. Retinal imaging can be performed using digital retinal photographs with (mydriatic) or without (nonmydriatic) dilating of the pupil. One approach is mydriatic standard field 35-mm stereoscopic color fundus photography. Digital fundus photography has also been evaluated as an alternative to conventional film photography. Digital imaging has the advantage of easier acquisition, transmission, and storage. Digital images of the retina can also be acquired in a primary care setting and evaluated by trained readers in a remote location, in consultation with retinal specialists.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several digital camera and transmission systems (see Table 1 for examples) have been cleared for marketing by the U.S. FDA through the 510(k) process and are currently available. FDA product codes: HKI and NFJ. In 2018, the FDA gave De Novo clearance for the automated retinal analysis system (IDx-DR) that uses artificial intelligence (DEN180001). IDx-DR is indicated "for use by health care providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400. "

Table 1. Examples of Digital Camera and Transmission Systems Cleared by FDA for Retinal Telescreening

Camera and Transmission Systems	Manufacturer	FDA Clearance	Approved
RetinaVue™‡ Network REF 901108 PACS Medical Image System	Welch Allyn	K181016	2018
IRIS Intelligent Retinal Imaging System™‡	Ora Inc.	K141922	2015
EyeSuite Imaging	Haag-Streit AG	K142423	2014
CenterVue Digital Retinography System (DRS)	Welch Allyn	K101935	2010
ImageNet™‡ Digital Imaging System	Topcon Medical Systems		2008
The Fundus AutoImagerä	Visual Pathways		2002
Zeiss FF450 Fundus Camera and the VISUPAC®‡ Digital Imaging System	Carl Zeiss Meditec		2001
DigiScope®‡	Eye Tel Imaging with Johns Hopkins Medicine		1999

FDA: Food and Drug Administration.

Table 2. Automated Analysis Systems

Automated Analysis Systems	Manufacturer	Clearance	Approved
IDx-DR Artificial Intelligence Analyzer for the Topcon NW400	IDx, LLC	FDA De Novo	2018
EyeArt®‡	Eyenuk	CE	
RetmarkerDR	Retmarker	CE	
iGradingM	EMIS Health	CE	
Retinalyze	ReitnaLyze A/S	CE	

CE: Conformite Europeenne; FDA: Food and Drug Administration.

Rationale/Source

Retinopathy telescreening and risk assessment with digital imaging systems are proposed as an alternative to conventional dilated fundus examination in diabetic individuals. Digital imaging systems use a digital fundus camera to acquire a series of standard field color images and/or monochromatic images of the retina of each eye. Captured digital images may be transmitted via the Internet to a remote center for interpretation by trained readers, storage, and subsequent comparison.

For individuals who have diabetes without known diabetic retinopathy who receive digital retinal imaging with optometrist or ophthalmologist image interpretation, the evidence includes systematic reviews and a randomized controlled trial (RCT). Relevant outcomes include test validity, change in disease status, and functional outcomes. Data from systematic reviews have demonstrated there is concordance between direct ophthalmoscopy and grading by mydriatic or non-mydriatic photography and remote evaluation. An RCT that compared a telemedicine screening program with traditional surveillance found that patients who were randomized to the telemedicine arm were more likely to undergo screening (95% vs. 44%). There is limited direct evidence related to visual outcomes for patients evaluated with a strategy of retinal telescreening. However, given evidence from the Early Treatment Diabetic Retinopathy Study that early retinopathy treatment improves outcomes, coupled with studies showing high concordance between the screening methods used in

Early Treatment Diabetic Retinopathy Study, and an RCT demonstrating higher uptake of screening with a telescreening strategy, a strong chain of evidence can be made that telescreening is associated with improved health outcomes. Digital imaging systems have the additional advantages of short examination time and the ability to perform the test in the primary care physician setting. For individuals who cannot or would not be able to access an eye care professional at the recommended screening intervals, the use of telescreening has a low-risk and is very likely to increase the likelihood of retinopathy detection. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have diabetes without known diabetic retinopathy who receive digital retinal imaging with automated image interpretation, the evidence includes a prospective study comparing the validity of automated scoring of digital images to remote interpretation. Relevant outcomes are test validity, change in disease status, and functional outcomes. One automated artificial intelligence system for evaluating diabetic retinopathy in primary care has received De Novo marketing clearance from the U.S. FDA. The pivotal study for this system met its performance threshold compared to the criterion standard of expert photography and image evaluation from a centralized site with sensitivity of 87.2% and specificity of 90.7%. The positive predictive value, which would be an important determinant of the value of a screening method to refer to an ophthalmologist, was not included in the published report but could be calculated at 74.9%. Further study as the artificial intelligence system evolves is needed to determine whether the positive predictive value can approach that of an expert evaluator. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2011 addressed the need for pupil dilation in retinal telescreening and the use of retinal telescreening for individuals with diagnosed diabetic retinopathy. Although evidence has shown that digital imaging without mydriasis leads to an increase in the proportion of ungradable photographs, practice guidelines, and clinical input have supported the use of both dilated and undilated retinal telescreening.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers,

input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 academic medical centers and 1 physician specialty society while this policy was under review in 2011. Input supported the medical necessity of retinal telescreening when performed with or without dilation. Input was mixed on the use of retinal telescreening for monitoring and managing disease in individuals diagnosed with diabetic retinopathy. One reviewer commented that retinal telescreening could be useful for monitoring patients with stable disease, particularly in outlying areas where access to this technology exceeds access to ophthalmologists.

Practice Guidelines and Position Statements

American Diabetes Association
In 2020, the American Diabetes Association updated its guidelines on standards of medical care for diabetes. Included in the guidelines were specific recommendations for initial and subsequent screening examinations for retinopathy:

- "Adults with type 1 diabetes should have an initial eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. (B)"
- "Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of the diabetes diagnosis. (B)"
- "Eye examinations should occur before pregnancy or in the first trimester in patients with preexisting type 1 or type 2 diabetes, and then these patients should be monitored every trimester and for 1 year postpartum as indicated by the degree of retinopathy. (B)"
- "If there is no evidence of retinopathy for one or more annual eye exams and glycemia is well controlled, then screening every 1–2 years may be considered. (B)"
- "Programs that use retinal photography (with remote reading or use of a validated assessment tool) to improve access to diabetic retinopathy screening can be appropriate screening strategies for diabetic retinopathy. Such programs need to provide pathways for timely referral for a comprehensive eye examination when indicated. (B)"

"Artificial intelligence systems that detect more than mild diabetic retinopathy and diabetic macular edema authorized for use by the FDA represent an alternative to traditional screening approaches.

However, the benefits and optimal utilization of this type of screening have yet to be fully determined."

American Academy of Ophthalmology
In 2017, a preferred practice pattern from the American Academy of Ophthalmology has provided the following on screening for diabetic retinopathy: "The purpose of an effective screening program for diabetic retinopathy is to determine who needs to be referred to an ophthalmologist for close follow-up and possible treatment and who may simply be screened annually. Some studies have shown that screening programs using digital retinal images taken with or without dilation may enable early detection of diabetic retinopathy along with an appropriate referral."

American Telemedicine Association
In 2011, the American Telemedicine Association published guidelines on the clinical, technical, and operational performance standards for diabetic retinopathy screening. Recommendations were based on reviews of current evidence, medical literature, and clinical practice. The Association stated that Early Treatment Diabetic Retinopathy Study 30°, stereo 7-standard field, color 35-mm slides are an accepted standard for evaluating diabetic retinopathy. Although no standard criteria have been widely accepted as performance measurements of digital imagery used for diabetic retinopathy evaluation, clinical trials sponsored by the National Eye Institute have transitioned to digital images for diabetic retinopathy assessment. Telehealth programs for diabetic retinopathy should demonstrate an ability to compare favorably with Early Treatment Diabetic Retinopathy Study film or digital photography as reflected in κ values for agreement of diagnosis, false-positive and false-negative readings, positive predictive value, negative predictive value, sensitivity and specificity of diagnosing levels of retinopathy, and macular edema. Inability to obtain or read images should be considered a positive finding, and patients with unobtainable or unreadable images should be promptly reimaged or referred for evaluation by an eye care specialist.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination specific to retinal telescreening. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

There is a national coverage determination on intraocular photography, originally developed in 1979, which states:

"Intraocular photography is covered when used for the diagnosis of such conditions as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, or to identify glaucoma, multiple sclerosis and other central nervous system abnormalities. Make Medicare payment for the use of this procedure by an ophthalmologist [sic] in these situations when it is reasonable and necessary for the individual patient to receive these services."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03911323	A Prospective Clinical Study on the Real-world Diagnostic Effectiveness of Artificial Intelligence Algorithm in Diabetic Retinopathy Screening	1000	Oct 2020
Unpublished			
NCT03912961[a]	Comparative Analysis of Diabetic Retinopathy Images by Retina Specialists Versus EyeStar's Artificial Intelligence Software of Images Captured by Pictor Plus Retinal Camera	1000	May 2019
NCT03602989[a]	A Prospective, Multi-center Clinical Study on the Application of An Artificial Intelligence Enabled Disease Detection Software to Diabetic Retinopathy Screening Based on Fundus Images	1000	Aug 2019

NCT03572699	Simple, Mobile-based Artificial Intelligence AlgoRithms in the Detection of Diabetic ReTinopathy (SMART) Study	900	Oct 2018

NCT: national clinical trial.
a Industry sponsored or co-sponsored trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Retinal Telescreening for Diabetic Retinopathy", 9.03.13, April 2020.
2. Garg S, Davis RM. Diabetic retinopathy screening update. Clin Diabetes. 2009;27(4):140-145.
3. Early Treatment Diabetic Retinopathy Study Research Group. Fundus photographic risk factors for progression of diabetic retinopathy. ETDRS report number 12. Ophthalmology. May 1991;98(5 Suppl):823-833. PMID 2062515
4. Early Treatment Diabetic Retinopathy Study Research Group. Grading diabetic retinopathy from stereoscopic color fundus photographs--an extension of the modified Airlie House classification. ETDRS report number 10. Early Treatment Diabetic Retinopathy Study Research Group. Ophthalmology. May 1991;98(5 Suppl):786-806. PMID 2062513
5. American Diabetes Association. *Standards of Medical Care in Diabetes-2020* Abridged for Primary Care Providers. Clin Diabetes. 2020 Jan;38(1). PMID 31975748
6. Moss SE, Klein R, Kessler SD, et al. Comparison between ophthalmoscopy and fundus photography in determining severity of diabetic retinopathy. Ophthalmology. Jan 1985;92(1):62-67. PMID 2579361
7. Kinyoun JL, Martin DC, Fujimoto WY, et al. Ophthalmoscopy versus fundus photographs for detecting and grading diabetic retinopathy. Invest Ophthalmol Vis Sci. May 1992;33(6):1888-1893. PMID 1582794
8. Shi L, Wu H, Dong J, et al. Telemedicine for detecting diabetic retinopathy: a systematic review and meta-analysis. Br J Ophthalmol. Jun 2015;99(6):823-831. PMID 25563767
9. Bragge P, Gruen RL, Chau M, et al. Screening for presence or absence of diabetic retinopathy: a meta-analysis. Arch Ophthalmol. Apr 2011;129(4):435-444. PMID 21149748
10. Mansberger SL, Sheppler C, Barker G, et al. Long-term comparative effectiveness of telemedicine in providing diabetic retinopathy screening examinations: a randomized clinical trial. JAMA Ophthalmol. May 2015;133(5):518-525. PMID 25741666

11. Abramoff, MD, Lavin, PT, Birch, M, Shah, N, Folk, JC. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary. npj Digital Medicine (2018) 1:39 ; doi:10.1038/s41746-018-0040-6
12. Abramoff MD, Lou Y, Erginay A, et al. Improved automated detection of diabetic retinopathy on a publicly available dataset through integration of deep learning. Invest Ophthalmol Vis Sci. Oct 01 2016;57(13):5200-5206. PMID 27701631
13. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern Guidelines: Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2017.
14. Li HK, Horton M, Bursell SE, et al. Telehealth practice recommendations for diabetic retinopathy, second edition. Telemed J E Health. Dec 2011;17(10):814-837. PMID 21970573
15. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Intraocular Photography (80.6). 1979; https://www.cms.gov/medicare-coverage-database/details/ncd- details.aspx?NCDId=56&ncdver=1&bc=AgAAQAAAAAAA&.

Policy History

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06/20/2003	Medical Policy Committee review
08/25/2003	Managed Care Advisory Council approval
11/02/2004	Medical Director review
11/16/2004	Medical Policy Committee review. Format revision. No substance change to policy.
11/29/2004	Managed Care Advisory Council approval
10/05/2005	Medical Director review
10/18/2005	Medical Policy Committee review Format revision. FDA information added to policy. Rationale/Source added from BCBSA policy. No substance change to policy.
10/27/2005	Quality Care Advisory Council approval
11/01/2006	Medical Director review
11/15/2006	Medical Policy Committee approval. Diabetic Association recommendations for diabetic retinopathy screening were added to policy.
11/07/2007	Medical Director review
11/15/2007	Medical Policy Committee approval. Policy statement unchanged.

11/05/2008	Medical Director review
11/18/2008	Medical Policy Committee approval. No change to coverage eligibility.
12/04/2009	Medical Director review
12/16/2009	Medical Policy Committee approval. No change to coverage eligibility.
12/01/2010	Medical Director review
12/15/2010	Medical Policy Committee approval. No change to coverage eligibility.
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. Title changed from "Digital Imaging Systems for the Detection and Evaluation of Diabetic Retinopathy" to "Retinal Telescreening for Diabetic Retinopathy". Eligible for coverage statement revised to adopt the new policy title. Investigational statement added for all other indications of retinal telescreening. Background/Overview, Rationale and References revised and updated.
12/06/2012	Medical Policy Committee review
12/19/2012	Medical Policy Implementation Committee approval. No change to coverage.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. No change to coverage.
12/04/2014	Medical Policy Committee review
12/17/2014	Medical Policy Implementation Committee approval. No change to coverage.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. No change to coverage. Chart revised.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. No change to coverage.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. No change to coverage.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Added "Based on review of available data, the Company considers digital retinal imaging with automated image

	interpretation for the detection of diabetic retinopathy to be investigational." Chart updated.
12/11/2020	Coding update

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	92227, 92228 Code added eff 1/1/2021: 92229

HCPCS	No codes
ICD-10 Diagnosis	C92.01, C92.41, C92.51, C92.61, C92.A1, E08.11-E08.9, E09.11-E09.9, E10.311-E10.9, E11.0-E11.9, E13.0-E13.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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