



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA  
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/28/23  
LAST REVIEW DATE: 09/03/24  
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LAST CRITERIA REVISION DATE: 09/28/23  
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

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## OPTICAL COHERENCE TOMOGRAPHY FOR IMAGING OF CORONARY ARTERIES

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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## OPTICAL COHERENCE TOMOGRAPHY FOR IMAGING OF CORONARY ARTERIES

### Description:

Optical Coherence Tomography (OCT) is an imaging technique that uses near-infrared light to image the coronary arteries and has been proposed as an alternative to intravascular ultrasound (IVUS). OCT has higher resolution than IVUS but more shallow penetration of tissue. OCT has been investigated in the evaluation of coronary artery plaques for risk stratification, as an adjunct to percutaneous coronary intervention (PCI) and for follow-up evaluation of stent placement.

Several optical coherence tomography systems have been cleared for marketing through the U.S. Food and Drug Administration (FDA) 510(k) process. FDA approved devices include the following:

- C7 XR™ Imaging System
- C7 XR™ Imaging System with Fractional Flow Reserve
- Genuity® HF-OCT Imaging System
- HyperVue™ Imaging System
- ILUMIEN OPTIS™
- OPTIS™ Integrated System
- OPTIS™ Mobile System
- OPTIS™ Next Imaging System
- OPTIS™ Systems
- SpectraWAVE Imaging System

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### Criteria:

- Optical Coherence Tomography (OCT) is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- As an adjunct to percutaneous coronary interventions with stenting
- Risk stratification of intracoronary atherosclerotic plaques
- Follow-up evaluation of stenting

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## OPTICAL COHERENCE TOMOGRAPHY FOR IMAGING OF CORONARY ARTERIES

### Resources:

Literature reviewed 09/03/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 09/03/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Abbott JD, Cutlip D. Percutaneous coronary intervention with intracoronary stents: Overview. In: Dardas TF, ed. *UpToDate*. UpToDate; 2024. Accessed August 6, 2024. <https://www.uptodate.com/contents/percutaneous-coronary-intervention-with-intracoronary-stents-overview>
2. Akase H, Okamura T, Nagoshi R, et al. Risk Assessment of Side Branch Compromise After Coronary Bifurcation Stenting - A Substudy of the 3D-OCT Bifurcation Registry. *Circ J*. May 24 2024;88(6):959-969. doi:10.1253/circj.CJ-22-0723
3. Ali ZA, Landmesser U, Maehara A, et al. OCT-Guided vs Angiography-Guided Coronary Stent Implantation in Complex Lesions: An ILUMIEN IV Substudy. *Journal of the American College of Cardiology*. Jul 23 2024;84(4):368-378. doi:10.1016/j.jacc.2024.04.037
4. Aurigemma C, Ding D, Tu S, et al. Three-Year Clinical Impact of Murray Law-Based Quantitative Flow Ratio and OCT- or FFR-Guidance in Angiographically Intermediate Coronary Lesions. *Circ Cardiovasc Interv*. May 2024;17(5):e013191. doi:10.1161/circinterventions.123.013191
5. Dall'Orto CC, Ferreira Lopes RP, Eurípedes LV, Pinto Filho GV, da Silva MR. Acute Coronary Syndrome with Non-Obstructive Plaque on Angiography and Features of Vulnerable Plaque on Intracoronary Optical Coherence Tomography. *Diagnostics (Basel)*. Oct 3 2023;13(19)doi:10.3390/diagnostics13193118
6. Garcia-Garcia HM, Waksman R, Melaku GD, et al. Temporal changes in coronary plaque as assessed by an artificial intelligence-based optical coherence tomography: from the first-in-human trial on DREAMS 3G scaffold. *European heart journal cardiovascular Imaging*. Mar 27 2024;25(4):491-497. doi:10.1093/ehjci/jead299
7. Imamura M, Yunoki K, Miyahara K, Oka T. Unusual optical coherence tomography findings resembling sea anemone tentacles after orbital atherectomy for nodular calcification lesions in a haemodialysis patient: a case report. *Eur Heart J Case Rep*. Mar 2024;8(3):ytae095. doi:10.1093/ehjcr/ytae095
8. Los J, Mensink FB, Mohammadnia N, et al. Invasive coronary imaging of inflammation to further characterize high-risk lesions: what options do we have? *Front Cardiovasc Med*. 2024;11:1352025. doi:10.3389/fcvm.2024.1352025

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## **OPTICAL COHERENCE TOMOGRAPHY FOR IMAGING OF CORONARY ARTERIES**

9. Poon EKW, Wu X, Dijkstra J, et al. Angiography and optical coherence tomography derived shear stress: are they equivalent in my opinion? *Int J Cardiovasc Imaging*. Oct 2023;39(10):1953-1961. doi:10.1007/s10554-023-02949-0
10. Sreenivasan J, Reddy RK, Jamil Y, et al. Intravascular Imaging-Guided Versus Angiography-Guided Percutaneous Coronary Intervention: A Systematic Review and Meta-Analysis of Randomized Trials. *J Am Heart Assoc*. Jan 16 2024;13(2):e031111. doi:10.1161/jaha.123.031111
11. U.S. Food & Drug Administration (FDA). OPTIS Mobile System 510(k) Summary. 2023. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf23/K232386.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf23/K232386.pdf)
12. U.S. Food & Drug Administration (FDA). OPTIS Mobile System 510(k) Summary. 2015. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K152120.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/K152120.pdf)
13. U.S. Food & Drug Administration (FDA). HyperVue Imaging System 510(k) Summary. 2023. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf23/K230691.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230691.pdf)
14. U.S. Food & Drug Administration (FDA). SpectraWAVE Imaging System 510(k) Summary. 2023. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf22/K221257.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221257.pdf)
15. U.S. Food & Drug Administration (FDA). OPTIS Next Imaging System 510(k) Summary. 2021. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf21/K210458.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210458.pdf)
16. U.S. Food & Drug Administration (FDA). Genuity HF-OCT Imaging System 510(k) Summary. 2020. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/K192922.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192922.pdf)
17. U.S. Food & Drug Administration (FDA). OPTIS Systems 510(k) Summary. 2019. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/K183320.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183320.pdf)
18. U.S. Food & Drug Administration (FDA). OPTIS Integrated System 510(k) Summary. 2015. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K151286.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/K151286.pdf)
19. U.S. Food & Drug Administration (FDA). ILUMIEN OPTIS 510(k) Summary. 2015. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K150878.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/K150878.pdf)
20. U.S. Food & Drug Administration (FDA). C7 XR Imaging System with Fractional Flow Reserve 510(k) Summary. Updated 2011. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf11/K111201.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf11/K111201.pdf)
21. U.S. Food & Drug Administration (FDA). C7 XR Imaging System 510(k) Summary. 2010. Accessed August 7, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf9/K093857.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf9/K093857.pdf)



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22. Weissman NJ, Muhlestein JB. Intravascular ultrasound, optical coherence tomography, and angiography of coronary circulation. In: Dardas TF, ed. *UpToDate*. UpToDate; 2024. Accessed August 6, 2024. <https://www.uptodate.com/contents/intravascular-ultrasound-optical-coherence-tomography-and-angiography-of-coronary-circulation>

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### Coding:

CPT: 92978, 92979

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### History:

### Date:

### Activity:

Medical Policy Panel	09/03/24	Review with revisions
Medical Director (Dr. Raja, Dr. Sutanto)	08/01/24	Review with no revisions
Medical Policy Panel (ad hoc)	09/28/23	Review with revisions

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### Policy Revisions:

09/03/24 Updated: Description section; Resource section



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalín, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi: اگر شما، یا کسی که شما به او کمک میکنید، سوال در مورد Blue Cross Blue Shield of Arizona، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید].

Assyrian: Blue Cross Blue Shield of Arizona دهێت پێوهێنی به ههڵمێنەرێکی کهێh...

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณกำลังช่วยเหลือคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณจะได้รับความช่วยเหลือและขอมูลในภาษา ของคุณได้โดยไมม่ค่าใช้จ่าย โปรดขยมลาม โทร 877-475-4799