BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Total Ankle Replacement

Policy #: 339
Category: Surgery

Latest Review Date: June 2021
Policy Grade: **Effective July 24, 2014: Active Policy but no longer scheduled for regular literature reviews and updates.**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **total ankle replacement** using an FDA-approved device as a **covered** benefit in skeletally mature patients with moderate to severe ankle (tibiotalar) pain that limits daily activity and who have the following conditions:

- Arthritis in adjacent joints (i.e., subtalar or midfoot); **OR**
- Severe arthritis of the contralateral ankle; **OR**
- Arthrodesis of the contralateral ankle; **OR**
- Inflammatory (e.g., rheumatoid) arthritis

AND absence of the following contraindications:

- Extensive avascular necrosis of the talar dome;
- Compromised bone stock or soft tissue (including skin and muscle);
- Severe malalignment (e.g., > 15 degrees) not correctable by surgery;
- Active ankle joint infection;
- Peripheral vascular disease;
- Charcot neuroarthropathy.
- Peripheral neuropathy;
- Ligamentous instability;
- Subluxation of the talus;
- History of ankle joint infection;
- Presence of severe deformities above or beneath the ankle.

Blue Advantage will treat **revision or replacement of an implanted total ankle prosthesis** as a **covered benefit** for failure of a previously implanted ankle prosthesis (e.g., implant loosening, malpositioning, periprosthetic, infection, or periprosthetic fracture).

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

A variety of total ankle replacement (TAR) system designs, including fixed-bearing and mobile-bearing, are being investigated for the management of moderate-to-severe tibiotalar pain. TAR (arthroplasty) is being evaluated as an alternative to tibiotalar fusion (arthrodesis) in patients with arthritis.

The ankle joint is a comparatively small joint relative to the weight bearing and torque it must withstand. These factors have made the design of total ankle joint replacements technically challenging. The main alternative to total ankle replacement is arthrodesis. While both procedures are designed to reduce pain, the total ankle replacement is also intended to improve function and reduce stress on adjacent joints. TAR has been investigated since the 1970s, but the procedure was essentially abandoned in the 1980s due to a high long-term failure rate, both in terms of pain control and improved function. Newer models have since been developed, which can be broadly subdivided into two design types, fixed-bearing and mobile-bearing. More than twenty different ankle replacement systems are currently being evaluated worldwide.

Total ankle replacement has been performed in patients with severe rheumatoid arthritis, severe osteoarthritis, or post-traumatic osteoarthrosis. In general, patients selected for arthroplasty would not be good candidates for arthrodesis due to the presence of bilateral or subtalar arthritis or Chopart arthrosis. Optimal candidates for total ankle replacement are considered to be older (age > 50), thin, low-demand individuals with minimal deformity. Patients should have no functional barriers to participation in a rehabilitation program.

KEY POINTS:

Summary of Evidence

The established standard for the painful arthritic ankle is fusion, which usually results in a pain-free but rigid ankle in the short term. Complications associated with ankle fusion are non-union, an increase in arthrosis, and pain in adjoining joints, and not uncommonly, amputation. For specific conditions, including presence of bilateral, subtalar or midfoot arthritis, fusion is not indicated. Therefore, in the absence of an established alternative for specific conditions, total ankle replacement may be considered medically necessary when those specified conditions are met.

Practice Guidelines and Position Statements

American Orthopaedic Foot and Ankle Society (AOFAS)

The AOFAS Position Statement on The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle (approved April 2018) concludes "Ankle arthritis is a condition that can result in substantial pain and dysfunction. The American Orthopaedic Foot & Ankle Society supports the use of total ankle replacement as an option for the treatment of ankle arthritis that has failed conservative management in select patients due to its demonstrated improved outcomes in multiple peer reviewed publications."

American College of Foot and Ankle Surgeons (ACFAS)

The ACFAS Position Statement on Total Ankle Replacement Surgery (February 2020) notes that not every patient with end-stage arthritis of the ankle is a sound candidate for ankle replacement. A surgeon experienced in total ankle surgery can make this determination through careful history and physical evaluation. In the United States, total ankle replacement surgery is currently a safe and effective treatment option for select patients with end stage ankle arthritis. Studies have shown total ankle replacement surgery improves patient function, reduces pain, and promotes improved quality of life.

American Academy of Orthopaedic Surgeons (AAOS)
AAOS published a 2010 technology overview of surgical treatment options for patients with ankle arthritis in whom nonoperative treatment has failed. The report concluded that based on low- and very low-quality evidence, treatment of ankle arthritis with either a Generation 2 or Generation 3 total ankle arthroplasty results in an improvement in pain and function. The literature does not conclusively demonstrate predictors of better or worse patient-oriented outcomes (e.g., device failure, reoperation, pain relief, patient satisfaction, walking ability) for total ankle arthroplasty.

Additionally, the report concluded that there is limited data from multiple studies directly comparing the efficacy of total ankle arthroplasty to arthrodesis in patients with arthritis. The disparate preoperative ankle function scores and demographic characteristics between the groups enrolled in the relevant comparative studies prohibit meaningful comparisons and confound the interpretation of the data. Analysis of adverse events that corrected for preoperative differences in patients characteristics, provide conflicting results.

National Institute for Health and Clinical Excellence (NICE)
NICE considers total ankle replacement surgery standard clinical practice with an efficacy and safety profile that is sufficiently well-known.

KEY WORDS:
Agility ankle, ankle replacement, total ankle arthroplasty, ankle, total ankle replacement, ankle arthrodesis

APPROVED BY GOVERNING BODIES:
Fixed-bearing designs lock the polyethylene component into the baseplate, which provides greater stability but increases constraint and edge-loading stress at the bone implant interface, potentially increasing risk of early loosening and failure. In 2002, the U.S. Food and Drug Administration (FDA) approved the Agility® Ankle Revision Prosthesis (DePuy Orthopaedics), which is intended for cemented use only in patients with a failed previous ankle surgery. In 2005, the FDA reviewed a 510(k) marketing clearance application for the Topez™ Total Ankle Replacement (Topez Orthopedics, Inc., Boulder, Colorado) and determined that it was substantially equivalent to the existing DePuy Agility device. The Topez Ankle is now called the InBone™ Total Ankle System (Wright Medical Technology, Arlington, TN). This device is also intended for cemented use only. The Agility LP (DePuy Orthopaedics) and the Eclipse (Kinetikos Medical, Carlsbad, CA) received 510(k) marketing clearance in 2006. The SALTO Talaris® (Tornier, Edina, MN) received 510(k) marketing clearance in 2006 and 2009. These semi-constrained cemented prostheses are indicated in patients with end-stage ankle disorders (e.g., affected with severe rheumatoid, post-traumatic, or degenerative arthritis) as an alternative to ankle fusion.

Three-piece mobile-bearing systems have a polyethylene component that is unattached and articulates independently with both the tibial and talar components. The three-piece mobile-bearing prostheses are designed to reduce constraint and edge-loading but are less stable than

fixed-bearing designs and have the potential for dislocation and increased wear of the polyethylene component. Mobile-bearing designs are intended for uncemented implantation and have a porous coating on the components to encourage osseointegration. They include the Ankle Evolution System (AES, Biomet, Whippany, NJ), Buechel- Pappas system, HINTEGRA® Total Ankle Prosthesis (New Deal), Mobility™ Total Ankle System (DePuy), Salto Total Ankle Prosthesis (Tornier), Scandinavian Total Ankle Replacement (STAR, Small Bone Innovations, Morrisville, PA), Bologna and Oxford Universities (BOX) Ankle (MAT Ortho), CCI Evolution Ankle (Van Straten), Zenith (Corin) and the TNK ankle (Kyocera Corporation, Kyoto, Japan). Three-component mobile-bearing systems are Class III devices and are considered under a different regulatory pathway (premarket approval) than the fixed component devices described above, which were cleared for marketing under the 510(k) regulatory pathway. Premarket approval (PMA) requires demonstration of clinical efficacy in FDA-regulated trials conducted under an investigational device exemption (IDE). In May 2009, the FDA approved the STAR ankle as an alternative to fusion for replacing an ankle joint deformed by rheumatoid arthritis, primary arthritis, or post-traumatic arthritis. As a condition of the approval, the device maker must evaluate the safety and effectiveness of the device over the next eight years. The Mobility™ Total Ankle System is currently being evaluated in a FDA-regulated investigational device exemption (IDE) trial. The Ankle Evolution System (AES), Buechel-Pappas, Mobility, Salto Total Ankle, BOX Ankle, CCI Evolution Ankle, Zenith, and the TNK ankle are not currently used in the United States.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle

REFERENCES:

1. Adukia V, Mangwani J, Issac R, Hussain S, Parker L. Current concepts in the management of ankle arthritis. J Clin Orthop Trauma. 2020 May-Jun;11(3):388-398.
2. Agility-Ankle Revision Prosthesis 510(k) Summary. www.fda.gov/cdrh/pdf2/k020541.pdf.
3. American Academy of Orthopaedic Surgeons (AAOS). Technology Overview. The surgical treatment of ankle arthritis. 2010. https://www.aaos.org/research/overviews/AnkleArthritis_surgical.pdf.

4. American College of Foot and Ankle Surgeons (ACFAS). Position Statement on Total Ankle Replacement Surgery. February 2020. https://www.acfas.org/Health-Policy-and-Advocacy/Policy-Statements/Position-Statements/
5. American Orthopaedic Foot & Ankle Society (AOFAS). Position Statement: The Use of Total Ankle Replacement for the Treatment of Arthritic Conditions of the Ankle. April 2018. https://www.aofas.org/research-policy/health-policy
6. Anderson T, Montgomery F and Carlsson A. Uncemented STAR total ankle prosthesis. Three to eight-year follow-up of fifty-one consecutive ankles. J Bone Joint Surg Am 2003; 85-A (7):1321-9.
7. Bonnin M, Gaudot F, Laurent JR et al. The Salto Total Ankle Arthroplasty: Survivorship and Analysis of Failures at 7 to 11 years. Clin Orthop Relat Res 2010; 469(1):225-36.
8. Brodsky JW, et al. Changes in gait following the Scandinavian total ankle replacement. Journal Bone Joint Surgery Am. 2011; 93:1890-6.
9. Brunner S, Barg A, Knupp M et al. The Scandinavian total ankle replacement: long-term, eleven to fifteen-year, survivorship analysis of the prosthesis in seventy-two consecutive patients. J Bone Joint Surg Am 2013; 95(8): 711-8.
10. Coetzee JC, Deorio JK. Total ankle replacement systems available in the United States. Instr Course Lect 2010; 59:367-74.
11. Conti SF and Wong YS. Complications of total ankle replacement. Foot Ankle Clin 2002; 7(4):791-807.
12. Conti SF, Bisignani G and Martin R. Update on total ankle replacement. Semin Arthroplasty Reconstruct Foot Ankle 1999; 10:62-71.
13. Cracchiolo, A, et al. Design features of current total ankle replacements: Implants and instrumentation. Journal American Academy Orthopedic Surgeons, September 2008; 16(9): 530-540.
14. Demetracopoulos CA, Cody EA, Adams SB Jr, DeOrio JK, Nunley JA et al. Outcomes of Total Ankle Arthroplasty in Moderate and Severe Valgus Deformity. Foot Ankle Spec. 2019 Jun;12(3):238-245.
15. Deorio JK, et al. Total ankle arthroplasty. Instruction Course Lectures 2008; 57: 383-413.
16. Doets HC, Brand R and Nelissen RG. Total ankle arthroplasty in inflammatory joint disease with use of two mobile-bearing designs. J Bone Joint Surg Am 2006; 88(6):1272-84.
17. Easley ME, Vertullo CJ, Urban WC, et al. Total ankle arthroplasty. J Am Acad Orthop Surg 2002; 10(3):157-67.
18. Fevang BT, et al. 257 ankle arthroplasties performed in Norway between 1994 and 2005. Acta Orthopedics, October 2007; 78(5): 575-583.
19. Giannini S, Romagnoli M, O'Connor JJ et al. Early clinical results of the BOX ankle replacement are satisfactory: a multicenter feasibility study of 158 ankles. J Foot Ankle Surg 2011; 50(6):641-7.
20. Glazebrook MA, Arsenault K, Dunbar M. Evidence-based classification of complications in total ankle arthroplasty. Foot Ankle Int 2009; 30(10):945-9.

21. Gougoulias N, Khanna A, Maffulli N. How successful are current ankle replacements?: a systematic review of the literature. Clin Orthop Relat Res 2010; 468(1):199-208.
22. Guyer AJ, et al. Current concepts review: Total ankle arthroplasty. Foot Ankle Int, February 2008; 29(2): 256-264.
23. Haddad SL, et al. Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis. A systematic review of the literature. Journal of Bone and Joint Surgery Am, September 2007; 89(9): 1899-1905.
24. Henricson A, et al. The Swedish Ankle Arthroplasty Register: An analysis of 531 arthroplasties between 1993 and 2005. Acta Orthopedics, October 2007; 78(5): 569-574.
25. Henricson A, Nilsson JA, Carlsson A. 10-year survival of total ankle arthroplasties: a report on 780 cases from the Swedish Ankle Register. Acta Orthop 2011; 82(6):655-9.
26. Hosman AH, et al. A New Zealand national joint registry review of 202 total ankle replacements followed for up to 6 years. Acta Orthopedics, October 2007; 78(5): 584-591.
27. Jensen NC, Linde F. Long-term follow-up on 33 TPR ankle joint replacements in 26 patients with rheumatoid arthritis. Foot Ankle Surg 2009; 15(3): 123-6.
28. Jeyaseelan L, Si-Hyeong Park S, Al-Rumaih H, Veljkovic A, Penner MJ, et al. Outcomes Following Total Ankle Arthroplasty: A Review of the Registry Data and Current Literature. Orthop Clin North Am. 2019 Oct;50(4):539-548.
29. Kanzaki N, Chinzei N, Yamamoto T, Yamashita T, Ibaraki K, Kuroda R. Clinical Outcomes of Total Ankle Arthroplasty With Total Talar Prosthesis. Foot Ankle Int. 2019 Aug;40(8):948-954.
30. Kim HJ, Suh DH, Yang JH, Lee JW, Kim HJ, et al. Total ankle arthroplasty versus ankle arthrodesis for the treatment of end-stage ankle arthritis: a meta-analysis of comparative studies. Int Orthop. 2017 Jan;41(1):101-109.
31. Kofoed H, Lundberg-Jensen A. Ankle arthroplasty in patients younger and older than 50 years: a prospective series with long-term follow-up. Foot Ankle Int 1999; 20(8):501-6.
32. Kokkonen A, Ikavalko M, Tiihonen R et al. High rate of osteolytic lesions in medium-term followup after the AES total ankle replacement. Foot Ankle Int 2011; 32(2):168-75.
33. Koo K, Liddle AD, Pastides PS, Rosenfeld PF. The Salto total ankle arthroplasty - Clinical and radiological outcomes at five years. Foot Ankle Surg. 2019 Aug;25(4):523-528.
34. Kopp FJ, Patel MM, Deland JT, et al. Total ankle arthroplasty with the Agility prosthesis: clinical and radiographic evaluation. Foot Ankle Int 2006; 27(2):97-103.
35. Krause FG, Windolf M, Bora B et al. Impact of complications in total ankle replacement and ankle arthrodesis analyzed with a validated outcome measurement. J Bone Joint Surg Am 2011; 93(9):830-9.
36. Kurokawa H, Taniguchi A, Morita S, Takakura Y, Tanaka Y. Total ankle arthroplasty incorporating a total talar prosthesis: a comparative study against the standard total ankle arthroplasty. Bone Joint J. 2019 Apr;101-B(4):443-446.
37. Mann JA, Mann RA, Horton E. Star Ankle: long-term results.Foot Ankle Int 2011; 32(5): 473-84.

38. Marks RM. Mid-Term Prospective Clinical and Radiographic Outcomes of a Modern Fixed-Bearing Total Ankle Arthroplasty. J Foot Ankle Surg. 2019 Nov;58(6):1163-1170.
39. Mehdi N, Bernasconi A, Laborde J, Lintz F. Comparison of 25 ankle arthrodeses and 25 replacements at 67 months' follow-up. Orthop Traumatol Surg Res. 2019 Feb;105(1):139-144.
40. Merrill RK, Ferrandino RM, Hoffman R, Ndu A, Shaffer GW. Comparing 30-day all-cause readmission rates between tibiotalar fusion and total ankle replacement. Foot Ankle Surg. 2019 Jun;25(3):327-331.
41. National Institute for Health and Clinical Excellence (NICE). Total ankle replacement surgery. 2010. https://www.guidance.nice.org.uk/IP/359.
42. Norvell DC, Ledoux WR, Shofer JB, Hansen ST, Davitt J, et al. Effectiveness and Safety of Ankle Arthrodesis Versus Arthroplasty: A Prospective Multicenter Study. J Bone Joint Surg Am. 2019 Aug 21;101(16):1485-1494.
43. Nunley JA, Adams SB, Easley ME, DeOrio JK. Prospective Randomized Trial Comparing MobileBearing and Fixed-Bearing Total Ankle Replacement. Foot Ankle Int. 2019 Nov;40(11):1239-1248.
44. Nunley JA, Caputo AM, Easley ME et al. Intermediate to long-term outcomes of the STAR Total Ankle Replacement: the patient perspective. J Bone Joint Surg Am 2012; 94(1):43-8.
45. Onggo JR, Nambiar M, Phan K, Hickey B, Galvin M, Bedi H. Outcome after total ankle arthroplasty with a minimum of five years follow-up: A systematic review and meta-analysis. Foot Ankle Surg. 2019 Jul 25. pii: S1268-7731(19)30111-0. [Epub ahead of print]
46. Palanca A, Mann RA, Mann JA, Haskell A. Scandinavian Total Ankle Replacement: 15-Year Follow-up. Foot Ankle Int. 2018 Feb;39(2):135-142.
47. Pyevich MT, Saltzman CL, Callaghan JJ, et al. Total ankle arthroplasty: a unique design. Two to twelve-year follow-up. J Bone Joint Surg Am 1998; 80(10):1410-20.
48. Rippstein PF, Huber M, Coetzee JC et al. Total ankle replacement with use of a new three-component implant. J Bone Joint Surg Am 2011; 93(15):1426-35.
49. Rodriguez D, Bevernage BD, Maldague P et al. Medium term follow-up of the AES ankle prosthesis: High rate of asymptomatic osteolysis. Foot Ankle Surg 2010; 16(2):54-60.
50. Roukis TS. Incidence of revision after primary implantation of the Agility total ankle replacement system: a systematic review. J Foot Ankle Surg 2012; 51(2):198-204.
51. Salzman CL, Mann RA, et al. Prospective controlled trial of STAR total ankle replacement versus ankle fusion: Initial results. Foot & Ankle International, July 2009, Vol. 30, No. 7, pp. 579-596.
52. San Giovanni TP, Keblish DJ, Thomas WH, et al. Eight-year results of a minimally constrained total ankle arthroplasty. Foot Ankle Int 2006; 27(6):418-26.
53. Schuberth JM, et al. Perioperative complications of the Agility total ankle replacement in 50 initial, consecutive cases. Journal of Foot, Ankle Surgery May 2006; 45(3): 139-146.

54. Schuh R, Hofstaetter J, Krismer M et al. Total ankle arthroplasty versus ankle arthrodesis. Comparison of sports, recreational activities and functional outcome. Int Orthop 2012; 36(6):1207-14.
55. Segal AD, Cyr KM, Stender CJ, Whittaker EC, Hahn ME, et al. A three-year prospective comparative gait study between patients with ankle arthrodesis and arthroplasty. Clin Biomech (Bristol, Avon). 2018 May;54:42-53.
56. Shane A, Sahli H. Total Ankle Replacement Options. Clin Podiatr Med Surg. 2019 Oct;36(4):597-607.
57. SooHoo NF, et al. Comparison of reoperation rates following ankle arthrodesis and total ankle arthroplasty. Journal Bone Joint Surgery Am, October 2007; 89(10): 2143-2149.
58. Spirit AA, et al. Complications and failure after total ankle arthroplasty. Journal Bone Joint Surgery Am, June 2004; 86-A(6): 1172-1178.
59. Takakura Y, Tanaka Y, Sugimoto K et al. Long-term results of arthrodesis for osteoarthritis of the ankle. Clin Orthop Relat Res 1999; (361):178-85.
60. U.S. Food and Drug Administration. STAR Ankle premarket approval panel meeting presentation 4-24-07. 2007. https://www.fda.gov/ohrms/dockets/ac/07/slides/2007-4299s1-01.pdf.
61. van der Plaat LW, Haverkamp D. Patient selection for total ankle arthroplasty. Orthop Res Rev. 2017 Jul 31;9:63-73.
62. Veljkovic AN, Daniels TR, Glazebrook MA, Dryden PJ, Penner MJ, et al. Outcomes of Total Ankle Replacement, Arthroscopic Ankle Arthrodesis, and Open Ankle Arthrodesis for Isolated Non-Deformed End-Stage Ankle Arthritis. J Bone Joint Surg Am. 2019 Sep 4;101(17):1523-1529.
63. Wood PL, Karski MT, Watmough P. Total ankle replacement: the results of 100 mobility total ankle replacements. J Bone Joint Surg Br 2010; 92(7):958-62.
64. Wood PL, Prem H, Sutton C. Total ankle replacement: medium-term results in 200 Scandinavian total ankle replacements. J Bone Joint Surg Br 2008; 90(5):605-9.
65. Wood PL, Sutton C, Mishra V et al. A randomised, controlled trial of two mobile-bearing total ankle replacements. J Bone Joint Surg Br 2009; 91(1):69-74.
66. Zhao H, Yang Y, Yu G et al. A systematic review of outcome and failure rate of uncemented Scandinavian total ankle replacement. Int Orthop 2011; 35(12):1751-8.

POLICY HISTORY:

Medical Policy Group, January 2009
Medical Policy Group, April 2009
Medical Policy Group, September 2009
Available for comment September 18-November 2, 2009
Medical Policy Group, November 2009
Medical Policy Group, October 2010
Medical Policy Group, October 2011
Medical Policy Group, November 2012
Medical Policy Group, August 2013

Medical Policy Group, October 2013
Medical Policy Group, July 2014
Medical Policy Group, October 2019
Medical Policy Group, June 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.