09-J1000-36

Original Effective Date: 09/15/11

Reviewed: 03/12/25

Revised: 04/15/25

Subject: Abiraterone Acetate (Yonsa®, Zytiga®) Tablet

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Prostate cancer remains the most common non-cutaneous malignancy among men worldwide. Prostate cancer is a complex disease, with many variable aspects of management. Prostate cancer is an androgen dependent disease that initially responds but later becomes resistant to established therapies that reduce circulating testosterone levels or inhibit androgen binding to androgen receptor (AR). Reactivation of the disease despite castrate levels of testosterone (<50 ng/dL) represents a transition to the lethal phenotype of castration-resistant prostate cancer (CRPC). This state is now recognized to be driven by AR signaling, in part due to overexpression of the androgen receptor itself. In addition, a small percentage of prostate cancer patients (~3%) may be initially diagnosed with metastatic, castration-sensitive prostate cancer (CSPC) for which management remains a challenge.

Abiraterone is a small molecule inhibitor of 17 alpha-monooxygenase, which is a member of the cytochrome P450 family that catalyzes the 17 alpha-hydroxylation of intermediates of steroid biosynthesis involved in testosterone synthesis. Abiraterone, as brand name Zytiga, was initially approved by the FDA in April 2011 in combination with low-dose prednisone for the treatment of men with metastatic CRPC who have received prior chemotherapy containing docetaxel. In December 2012, the approval of Zytiga was expanded to include the treatment of men with metastatic CRPC as a first-line option (prior to other chemotherapy). In February 2018, the Zytiga indication was broadened to include the treatment of patients with metastatic high-risk, castration-sensitive prostate cancer (CSPC). In May 2018 a new micronized (smaller particle size) abiraterone acetate product, Yonsa, was approved by the FDA via the 505(b)(2) New Drug Application processes for the treatment of patients with metastatic CRPC in combination with methylprednisolone. Yonsa differs from Zytiga in several important ways: (1) Zytiga has an additional FDA-approved indication of treatment of metastatic high-risk CSPC; (2) Yonsa is labeled to be used in combination with methylprednisolone, while Zytiga is labeled to be used

in combination with prednisone; (3) Yonsa is a micronized formulation with increase bioavailability and a labeled dosage of 500 mg daily, while Zytiga has a labeled dosage of 1,000 mg daily; (4) Yonsa is available as a 125 mg tablet only, while Zytiga is available as a 250 mg uncoated tablet, 250 mg film-coated tablet, and 500 mg film-coated tablet; and (5) Yonsa is labeled to be taken with or without food, while Zytiga must be given on an empty stomach either one hour before or two hours after a meal.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of abiraterone acetate (Yonsa, Zytiga) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

A. **ONE** of the following to support clinical use is met ("1", "2", or "3"):
   1. **BOTH** of the following are met regarding FDA labeling or NCCN Compendium ("a" and "b"):
      a. **EITHER** of the following (indication and usage) ["i" or "ii"]:
         i. Member is diagnosed with a condition that is consistent with an indication listed in the requested drug's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)
         ii. Indication **AND** usage are recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation (see Table 1)
      b. **EITHER** of the following (diagnostic testing) ["i" or "ii"]:
         i. The requested indication requires genetic/specific diagnostic testing per the FDA labeling* or NCCN Compendium, **AND BOTH** of the following are met:
            - The genetic/specific diagnostic testing has been completed
            - The results of the testing indicate therapy is appropriate – documentation must be submitted
         ii. The requested indication does **NOT** require specific genetic/diagnostic testing per FDA labeling or NCCN Compendium

         *FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools
   2. The requested agent is designated as an orphan drug by the FDA for the requested indication, **AND** the indication is not included in the FDA labeling or the NCCN compendium as a 1 or 2A recommendation (i.e., "Designated") [orphan drug designations can be found at http://www.accessdata.fda.gov/scripts/opdlisting/oopd/]

3. The indication and usage are supported by the results of **TWO** or more published clinical studies – the prescriber must submit full text copies of each article

   NOTE:

   - Case reports, posters, and abstracts (including published meeting abstracts) are **NOT** accepted as evidence to support use
   - Clinical studies must be supportive of use for a similar patient population (e.g., indication, diagnosis, disease severity, genetic or tumor mutations) and for the intended treatment plan, including any concomitant therapy

B. For brand Zytiga **ONLY** – **EITHER** of the following ("a" or "b"):

   a. Member has a contraindication to **BOTH** generic abiraterone **AND** Yonsa, and the contraindication is not applicable to brand Zytiga – the specific contraindication(s) and rationale for using brand Zytiga must be provided

   b. Member has tried and had intolerable adverse effects to **BOTH** generic abiraterone **AND** Yonsa, and the intolerance is not expected to occur with brand Zytiga - the specific intolerance(s) and rationale for using brand Zytiga must be provided. Also, **BOTH** of the following are required:

      i. A completed Medwatch reporting form (FDA 3500) must be submitted: https://www.fda.gov/safety/medical-product-safety-information/forms-reporting-fda

      ii. A completed Naranjo Adverse Drug reaction probability scale must be submitted: https://assets.guidewell.com/m/2736e82ff52fe22d/original/mcg-naranjo-algorithm.pdf

C. The dosage of the requested drug does not exceed the maximum FDA-approved dose and frequency with the following exceptions ("1" or "2"):

   i. Dose and frequency for the indication are supported by standard reference compendia (see NCCN Compendium or other compendia in Table 2)

   ii. Dose and frequency for the indication are supported by the results of **TWO** or more published clinical studies – the prescriber must submit full text copies of each article

   NOTE: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

D. The dose of the requested drug will be achieved using the fewest number of capsules or tablets per day **OR** does not exceed the quantity limit [http://www.bcbsfl.com/DocumentLibrary/Providers/Content/Rx_ResponsibleQuantity.pdf]

Approval duration: 6 months

Continuation of abiraterone acetate (Yonsa, Zytiga) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

A. The requested drug has been previously approved by Florida Blue or another health plan in the past 2 years, **OR** the member has previously met **ALL** indication-specific criteria

B. The dosage of the requested drug does not exceed the maximum FDA-approved dose and frequency with the following exceptions:

i. Dose and frequency for the indication are supported by standard reference compendia (see NCCN Compendium or Table 2)

ii. Dose and frequency for the indication are supported by the results of **TWO** or more published clinical studies – the prescriber must submit full text copies of each article

NOTE: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

C. The dose of the requested drug will be achieved using the fewest number of capsules or tablets per day **OR** does not exceed the quantity limit [http://www.bcbsfl.com/DocumentLibrary/Providers/Content/Rx_ResponsibleQuantity.pdf]

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

YONSA

FDA-approved: in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer (CRCP). The recommended dose is 500 mg (four 125 mg tablets) administered orally once daily in combination with methylprednisolone 4 mg administered orally twice daily. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. To avoid medication errors and overdose, be aware that Yonsa tablets may have different dosing and food effects than other abiraterone acetate products. Unlike Zytiga, Yonsa tablets can be taken with or without food. The tablets should be swallowed whole with water. Do not crush or chew tablets.

Dose Adjustments

- **Baseline moderate hepatic impairment**: For members with moderate hepatic impairment (Child-Pugh class B), the initial dose should be reduced to 125 mg once daily. Do **NOT** use in patients with severe baseline hepatic impairment (Child-Pugh Class C). Monitor ALT, AST and bilirubin prior to therapy initiation, every week for 1 month, every 2 weeks for the following 2 months and monthly thereafter; if elevation in ALT and/or AST exceed 5 times the upper limit of normal (ULN) or total bilirubin exceeds 3 times the ULN, discontinue therapy and do not reinitiate.
- **Hepatotoxicity**: For members with normal hepatic function who develop hepatotoxicity while on therapy:
    - First elevation: ALT and/or AST greater than 5 times ULN or total bilirubin 3 times ULN interrupt therapy and reinitiate at 375 mg daily once members levels return to baseline or less than or equal to 2.5 times the ULN for ALT and/or AST or 1.5 times ULN for bilirubin. Monitor ALT, AST and bilirubin at a minimum of every two weeks for three months and monthly thereafter.

- Recurrence after reduction to 375 mg: reinitiate at 250 mg once daily once members LFTs to baseline or less than or equal to 2.5 times the ULN for ALT and/or AST or 1.5 times ULN for bilirubin
- Recurrence after reduction to 250 mg: discontinue therapy
- Permanently discontinue for patients who develop a concurrent elevation of ALT greater than 3 times ULN and total bilirubin greater than 2 times ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

- **Strong CYP3A4 Inducers**: Avoid concomitant strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital) during treatment if possible. Although there are no clinical data with this dose adjustment, because of the potential for an interaction, if a strong CYP3A4 inducer **MUST** be co-administered, increase the dosing frequency to twice a day only during the co-administration period (e.g., from 500 mg once daily to 500 mg twice a day). Reduce the dose back to the previous dose and frequency, if the concomitant strong CYP3A4 inducer is discontinued.

Drug Availability: Yonsa is supplied as a 125 mg tablet.

ZYTIGA

FDA-approved: in combination with prednisone for the treatment of persons with: (1) metastatic castration-resistant prostate cancer (CRPC), and (2) metastatic high-risk castration-sensitive prostate cancer (CSPC). Although initially approved for CRPC following chemotherapy, the indication was expanded in December 2012 to include treatment prior to treatment with chemotherapy, and then in February 2018 to include metastatic high-risk castration-sensitive prostate cancer (CSPC). Abiraterone should be administered as a 1,000 mg dose (two 500 mg or four 250 mg tablets) once daily in combination with prednisone (5 mg once daily for CSPC or 5 mg twice daily for CRPC). Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. Additionally, it should always be taken on an empty stomach to prevent supratherapeutic concentrations. The package insert advises against eating 2 hours before or 1 hour after administration. The tablets should be swallowed whole; do not crust or chew tablets.

Dose Adjustments

- **Baseline moderate hepatic impairment:** For members with moderate hepatic impairment (Child-Pugh class B), the initial dose should be reduced to 250 mg once daily. Do **NOT** use in patients with severe baseline hepatic impairment (Child-Pugh Class C). Monitor ALT, AST and bilirubin prior to therapy initiation, every week for 1 month, every 2 weeks for the following 2 months and monthly thereafter; if elevation in ALT and/or AST exceed 5 times the upper limit of normal (ULN) or total bilirubin exceeds 3 times the ULN, discontinue therapy and do not reinitiate.
- **Hepatotoxicity:** For members with normal hepatic function who develop hepatotoxicity while on therapy:
  - First elevation: ALT and/or AST greater than 5 times ULN or total bilirubin 3 times ULN interrupt therapy and reinitiate at 750 mg daily once members levels return to baseline or less than or equal to 2.5 times the ULN for ALT and/or AST or 1.5 times ULN for bilirubin. Monitor ALT, AST and bilirubin at a minimum of every two weeks for three months and monthly thereafter

- Recurrence after reduction to 750 mg: reinitiate at 500 mg once daily once members LFTs to baseline or less than or equal to 2.5 times the ULN for ALT and/or AST or 1.5 times ULN for bilirubin
- Recurrence after reduction to 500 mg: discontinue therapy
- Permanently discontinue for patients who develop a concurrent elevation of ALT greater than 3 times ULN and total bilirubin greater than 2 times ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

- **Strong CYP3A4 Inducers:** Avoid concomitant strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital) during treatment if possible. Although there are no clinical data with this dose adjustment, because of the potential for an interaction, if a strong CYP3A4 inducer **MUST** be co-administered, increase the dosing frequency to twice a day only during the co-administration period (e.g., from 1,000 mg once daily to 1,000 mg twice a day). Reduce the dose back to the previous dose and frequency, if the concomitant strong CYP3A4 inducer is discontinued.

Drug Availability: abiraterone is supplied as 250 mg film-coated and uncoated tablets and 500 mg film-coated tablets.

PRECAUTIONS:

YONSA and ZYTIGA

CONTRAINDICATIONS

- Pregnancy - can cause fetal harm and potential loss of pregnancy

WARNINGS

- **Hypokalemia, Fluid Retention, and Cardiovascular Adverse Reactions due to Mineralocorticoid Excess:** Abiraterone may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Use abiraterone with caution in members with a history of cardiovascular disease. The safety of abiraterone in members with a LVEF less than 50% or NYHA Class III or IV heart failure has not been established. Control hypertension and correct hypokalemia prior to treatment initiation. Monitor blood pressure, serum potassium and symptoms of fluid retention at least monthly. In the LATITUDE trial which used prednisone 5 mg daily in combination with 1000 mg abiraterone acetate daily, grades 3-4 hypokalemia were detected in 10% of patients on the abiraterone arm and 1% of patients on the placebo arm, grades 3-4 hypertension were observed in 20% of patients on the abiraterone arm and 10% of patients on the placebo arm. Grades 3-4 fluid retention occurred in 1% of patients each arm.
- **Adrenocortical insufficiency:** Monitor for symptoms and signs of adrenocortical insufficiency. Increased dosage of corticosteroids may be indicated before, during and after stressful situations.
- **Hepatotoxicity:** Increases in liver enzymes have led to drug interruption, dose modification and/or discontinuation. Monitor liver function and modify, interrupt, or discontinue abiraterone dosing as recommended.

- **Increased fractures and mortality in combination with radium Ra 223 dichloride:** Use of abiraterone plus prednisone/prednisolone in combination with radium Ra 223 dichloride is not recommended
- **Embryo-Fetal Toxicity** - The safety and efficacy of abiraterone have not been established in females. Based on animal reproductive studies and mechanism of action, abiraterone can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 weeks after the final dose. Abiraterone should not be handled by females who are or may become pregnant.
- **Hypoglycemia** - Severe hypoglycemia has been reported when abiraterone was administered to patients with pre-existing diabetes receiving medications containing thiazolidinediones (including pioglitazone) or repaglinide. Monitor blood glucose in patients with diabetes during and after discontinuation of treatment with abiraterone acetate. Assess if antidiabetic drug dosage needs to be adjusted to minimize the risk of hypoglycemia.
- **Food effect (Zytiga ONLY)** - Zytiga must be taken on an empty stomach. Exposure may increase up to 10-fold when abiraterone is taken with meals.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity

C06.9	Malignant neoplasm of mouth, unspecified
C07	Malignant neoplasm of parotid gland
C08.0 - C08.9	Malignant neoplasm of other and unspecified major salivary glands
C61	Malignant neoplasm of prostate

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

DEFINITIONS:

Castrate-resistant/recurrent prostate cancer (CRPC): disease progression despite androgen deprivation therapy (ADT) with either medication or surgery (i.e., removal/destruction of testicles, and may present as either a continuous rise in serum prostate-specific antigen (PSA) levels, the progression of pre-existing disease, and/or the appearance of new metastases.

TNM Classification of Malignant Tumors (TNM): a notation system that describes the stage of a cancer which originates from a solid tumor with alphanumeric codes. T describes the size of the original (primary) tumor and whether it has invaded nearby tissue. N describes nearby (regional) lymph nodes that are involved, M describes distant metastasis (spread of cancer from one part of the body to another).

RELATED GUIDELINES:

Cabazitaxel (Jevtana), 09-J1000-77
Cryosurgical Ablation of the Prostate (CSAP), 02-54000-14
Docetaxel (Taxotere) IV, 09-J0000-95
Gonadotropin Releasing Hormone Analogs and Antagonists, 09-J0000-48
Oral Oncology Medications, 09-J3000-65
Radium Ra 223 (Xofigo) Injection, 09-J2000-01
Sipuleucel-T (Provenge), 09-J1000-29

OTHER:

Table 1

NCCN Categories of Evidence Consensus	
Category 1	Based upon high-level evidence; there is uniform NCCN consensus that the intervention is appropriate
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2B	Based upon lower-level evidence, there NCCN consensus that the intervention is appropriate
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Table 2

Other Compendia	
Compendium	**Covered Uses**
AHFS-DI	Narrative text is supportive
Clinical Pharmacology	Narrative text is supportive
Lexicomp	Evidence rating A, B or G
Thomson Micromedex DrugDex	Meets requirements for **BOTH** of the following: • Strength of recommendation: Class I (Recommended) or IIa (Recommended, In Most Cases)

	• Efficacy: Class I (Effective) or IIa (Evidence Favors Efficacy)
AHFS-DI - American Hospital Formulary Service Drug Information	

Table 3

Lexicomp Recommendation Ratings	
A	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (e.g., results of the introduction of penicillin treatment) to support the off-label use. Further research is unlikely to change confidence in the estimate of benefit.
B	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.
C	Evidence from observational studies (e.g., retrospective case series/reports providing significant impact on patient care), unsystematic clinical experience, or from potentially flawed randomized, controlled trials (e.g., when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

Table 4

Thomson Micromedex DrugDex Recommendation Ratings: Strength of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered
Class IIa	Recommended, in most cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended in some cases	The given test or treatment may be useful, and is indicated in some, but not most, cases
Class III	Not recommended	The given test or treatment is not useful and should be avoided
Class Indeterminate	Evidence Inconclusive	

Table 5

Thomson Micromedex DrugDex Recommendation Ratings: Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence favors efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.

Class IIb	Evidence is inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective

REFERENCES:

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2. de Bono JS, Logothetis CJ, Molina A, et al. Abiraterone and increased survival in metastatic prostate cancer. N Engl J Med. 2011 May 26;364(21):1995-2005.
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14. Yonsa (abiraterone acetate) [package insert]. Sun Pharmaceutical Industries, Inc. Cranbury (NJ): July 2022.
15. Zytiga (abiraterone acetate) [package insert]. Janssen Biotech, Inc. Horsham (PA): November 2024.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 03/12/25.

GUIDELINE UPDATE INFORMATION:

09/15/11	New Pharmacy Coverage Guideline.
11/15/11	Revision to guideline; consisting of removing 18 years of age requirement for coverage.
09/15/12	Review and revision to guideline; consisting of updating position statement, precautions and references.
02/15/13	Revision to guideline; consisting of adding additional indication to position statement, revising and reformatting description, dosage/administration, precautions section; adding definition and related guidelines; updating references.
04/15/13	Review and revision to guideline; consisting of revising position statement to include approval duration; updating description section and references.
04/15/14	Review and revision to guideline; consisting of reformatting position statement, updating description section, references and program exceptions.
04/15/15	Review and revision to guideline; consisting of description section, position statement to include continuation criteria, dosage/administration, definitions, and references.
04/15/16	Review and revision to guideline consisting of description section, position statement, definitions, and references.
04/15/17	Review and revision to guideline consisting of description section, position statement, precautions section, and references.
07/01/17	Revision to guideline consisting of updating the position statement and dosage/administration section as a result of a new 500 mg tablet strength.
04/15/18	Review and revision to guideline consisting of description section, position statement, precautions section, definitions, and references.
09/15/18	Revision to guideline consisting of description section, position statement, dosage/administration section, precautions section, definitions, and references based on the approval of Yonsa.
12/15/18	Revision to guideline consisting of updating the position statement.
04/15/19	Review and revision to guideline consisting of updating the description section, position statement, and references.
04/15/21	Review and revision to guideline consisting of updating the description section, position statement, other guidelines, and references.
04/15/22	Review and revision to guideline consisting of updating the warnings and references.
04/15/23	Review and revision to guideline consisting of updating the references.
04/15/24	Review and revision to guideline consisting of updating the position statement, billing/coding, and references.
04/15/25	Review and revision to guideline consisting of updating the precautions and references.