Elective Delivery of Pregnancy

Policy # 00422
Original Effective Date: 09/01/2014
Current Effective Date: 09/14/2020

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.*

Women at Term Gestation (39 weeks gestation or greater)
Based on review of available data, the Company may consider labor inductions and elective Cesarean delivery in women at 39 weeks or greater in pregnancy to be **eligible for coverage.****

The decision for timing of such delivery should be one between the member and her provider, weighing both benefits and risks of induction. These should include history of prior delivery, cervical status, maternal health, and fetal status. The decision should not be typically based solely on gestational age.

Women at Preterm Gestational ages (<39 weeks) who have fetal or maternal indication for delivery

Based on review of available data, the Company may consider labor inductions and elective Cesarean delivery in women <39 weeks gestation when there are established maternal and/or fetal risks in which the risk of continuing the pregnancy outweighs the risks of early birth to be **eligible for coverage.****

The member should have a clear understanding of the risks/ benefits from early delivery with documentation of the risks/benefits. Maternal-Fetal-Medicine evaluation and delivery recommendations should be obtained as clinically available and appropriate.

Elective Delivery of Pregnancy

Policy # 00422
Original Effective Date: 09/01/2014
Current Effective Date: 09/14/2020

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers an elective induction of labor or elective Cesarean delivery, without specialty accepted maternal and/or fetal indications for delivery, prior to 39 weeks gestation to be **not medically necessary.****

Based on review of available data, the Company considers all services- including provider, facility and other related charges- in conjunction with such non-medically indicated delivery prior 39 weeks gestation will be considered **not medically necessary.****

Background/Overview

Gestation in singleton pregnancies lasts an average of 40 weeks (280 days) from the first day of the last menstrual period to the estimated date of delivery. Preterm birth is that delivery which occur prior 37 weeks gestation in a pregnancy having achieved at least 20 weeks. Previously, the period from 3 weeks before until 2 weeks after the estimated date of delivery was considered "term", with the expectation that neonatal outcomes from deliveries in this interval were uniform and good. Increasingly, however, research has identified that neonatal outcomes, especially respiratory morbidity, vary depending on the timing of delivery even within this 5-week gestational age range. The frequency of adverse neonatal outcomes is lowest among uncomplicated pregnancies delivered between 39 0/7 weeks of gestation and 40 6/7 weeks of gestation. For this reason, groups such as the American College of Obstetricians and Gynecologists (ACOG), March of Dimes, and the National Institute of Health have focused on eliminating non-medically indicated deliveries at less than 39 0/7 weeks of gestation. Most major birthing centers have pledged to eliminate elective early inductions and some payers, both Commercial and Medicaid, have adopted non-reimbursement policies for elective delivery prior 39 weeks as not medically necessary.

An elective induction of labor or delivery is one in which there are no clear medical benefits to mother or fetus for delivery at that point in time as compared with continuation of pregnancy. In contrast, a medically indicated induction of labor is noted by a clear medical benefit to either mother or baby from ending the pregnancy rather than continuing it. Evidence has suggested that the non-medically indicated elective induction performed prior to 39 weeks have risen sharply in the United States. The reported rate of labor induction in the U.S has more than doubled since 1990, from 9.5% to 22.5% in 2006. While the increased rates of inductions are noted in all racial and ethnic groups it is greatest in non-Hispanic whites. These elective inductions are associated with increases in

Elective Delivery of Pregnancy

Policy # 00422
Original Effective Date: 09/01/2014
Current Effective Date: 09/14/2020

Cesarean deliveries, increased rates of late preterm births, and increased neonatal intensive care unit (NICU) admissions. While efforts for elimination of elective induction prior 39 weeks has made progress, there is evidence that about 5% of inductions remain in this category.

There are medical indications in pregnancy for which there is evidence or expert opinion to support expedient delivery in the early-term period versus expectant management. Pregnancies complicated by one of these findings may require early delivery. This list is not intended to be all inclusive of indications for early delivery, but serve as examples of maternal and fetal indications for such delivery. Consultation with Maternal Fetal Medicine (MFM) specialists is recommended and encouraged in the delivery decision process, especially if uncertainty on risks/benefits of delivery is present.

Examples of Medical Indications for Late-Preterm or Early-Term Deliveries:

- Preeclampsia, eclampsia, gestational hypertension, or complicated chronic hypertension
- Oligohydramnios
- Prior classical cesarean delivery or prior myomectomy
- Placenta previa or placenta accreta
- Multiple gestations
- Fetal growth restriction
- Pregestational diabetes with vascular disease
- Pregestational or gestational diabetes—poorly controlled
- Placental abruption
- Chorioamnionitis
- Premature rupture of membranes
- Cholestasis of pregnancy
- Alloimmunization of pregnancy with known or suspected fetal effects
  Fetal congenital malformations
- Fetal testing suggestive of intrauterine fetal compromise

The reasons for the increases in late preterm and early term elective inductions are felt to be complex. However, the roles of both providers and patients must be addressed. The underlying heart of the problem is often a lack of knowledge and awareness of the newborn risks associated with elective early delivery. In Goldenberg, et.al (2009) study of women's perceptions almost 50% of women felt that term was 37-38 weeks gestation and only 25% identified term as 39 weeks or greater. When

asked at what gestational age was it safe to electively deliver a pregnancy, over 50% of women identified 34-36 weeks gestation as safe. Only 7.6% felt that is was best to wait until 39-40 weeks for newborn safety. The risks of these early delivers were not generally comprehended.

Physicians provided a broad list of reasons for participating in elective early inductions. Reasons included patient demands for delivery and a limited understanding of newborn risks, with the thought that bad outcomes were rare and handled well by the NICU when they occurred. Physicians also cited limiting the risk of adverse outcome at a later gestational age. Physician convenience for both reducing scheduling conflicts and avoidance of interruptions at night and weekends was a factor but not primary in decision making.

Rationale/Source

Delivery Timing and Neonatal Outcomes

Preterm labor is defined as regular contractions of the uterus resulting in changes in the cervix that start before 37 weeks of pregnancy. These changes include effacement, or cervical thinning, and dilation. When birth occurs between 20 weeks of pregnancy and 37 weeks of pregnancy, it is called preterm birth, whether due to spontaneous labor or medical intervention for delivery. Preterm birth is a concern because babies who are born too early may face serious health problems, including respiratory, cardiac, neurological and gastrointestinal complications. Some health problems, like cerebral palsy, can last a lifetime. Other problems from preterm birth, such as learning disabilities, appear later in childhood or even in adulthood. The risk of health problems is greatest for babies born before 34 weeks of pregnancy. But babies born after 34 weeks also are at risk.

The ACOG and the Society for Maternal-Fetal Medicine (SMFM) are discouraging use of the general label ‘term pregnancy’ and replacing it with a series of more specific labels: ‘early term,’ ‘full term,’ ‘late term,’ and ‘post term.’ The following represent the four new definitions of ‘term’ deliveries:

- Early Term: Between 37 weeks 0 days and 38 weeks 6 days
- Full Term: Between 39 weeks 0 days and 40 weeks 6 days
- Late Term: Between 41 weeks 0 days and 41 weeks 6 days
- Postterm: Between 42 weeks 0 days and beyond

Research over the past several years shows that every week of gestation matters for the health of newborns. The last few weeks of pregnancy within these 40 weeks allow a baby's brain and lungs to more fully mature. Babies born between 39 weeks 0 days and 40 weeks 6 days gestation, at full term, have the best health outcomes, compared with babies born before or after this period. Planned deliveries before 39 weeks 0 days should occur only when there are significant health risks to a woman and/or the fetus in continuing the pregnancy.

Shapiro-Mendoza, et al, evaluated composite morbidity by gestational age at birth for over 400,000 newborns born between 34 and 40 weeks in Massachusetts. They found that morbidity rates almost doubled for each gestational week earlier than 38 weeks. The newborn morbidity by gestational week: 40 wks- 2.5%; 39 wks-2.6%; 38 wks- 3.3%; 37 wks- 5.9%; 36 wks- 12.1%; 35 wks- 25.6%; 34 wks- 51.9%.

Neonatal and Infant Morbidity and Mortality

The risk of adverse outcomes is greater for neonates delivered in the early-term period (37/38 weeks of gestation) compared with neonates delivered at 39 weeks of gestation. Because pulmonary development is not complete at birth and continues well into early childhood, respiratory morbidity is relatively common in neonates delivered in the early-term period. A retrospective cohort study by the Consortium on Safe Labor, which included 233,844 births, found that among all infants delivered at 37 weeks of gestation, regardless of indication, there were higher rates of respiratory failure (adjusted odds ratio [OR], 2.8; 95% confidence interval [CI], 2.0–3.9) and ventilator use (adjusted OR, 2.8; 95% CI, 2.3–3.4) compared with infants delivered at 39 weeks of gestation. In addition, higher rates of respiratory distress syndrome, transient tachypnea of the newborn, pneumonia, and surfactant and oscillator use were reported for infants delivered at 37 weeks of gestation compared with those delivered at 39 weeks of gestation. These complications result in higher rates and stays within the NICU. Slightly higher rates, but not statistically significant, of respiratory failure (adjusted OR, 1.4; 95% CI, 1.0–1.9) and ventilator use (adjusted OR, 1.2; 95% CI, 1.0–1.5) were reported for infants delivered at 38 weeks versus 39 weeks of gestation.

Neonatal Morbidities Associated With Early-Term Delivery

- Respiratory distress syndrome
- Transient tachypnea of the newborn
- Ventilator use
- Pneumonia

- Respiratory failure
- Neonatal intensive care unit admission
- Hypoglycemia
- 5-minute Apgar score less than 7
- Neonatal mortality

In a secondary analysis of data from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, neonates delivered during the early-term period by elective Cesarean delivery, were associated with a higher risk of a composite outcome of neonatal respiratory and nonrespiratory morbidities compared with neonates delivered at 39 weeks of gestation. Of these non-medically indicated deliveries, 35.8% were performed before 39 weeks of gestation. The rate of composite morbidity was higher for neonates delivered at 37 weeks of gestation (adjusted OR, 2.1; 95% CI, 1.7–2.5) and at 38 weeks of gestation (adjusted OR, 1.5; 95% CI, 1.3–1.7) compared with neonates delivered at 39 weeks of gestation. In addition, the morbidity for neonates delivered at 38 4/7–38 6/7 weeks of gestation remained significantly increased (relative risk, 1.21; 95% CI, 1.04–1.40). These findings suggest that scheduled elective Cesarean delivery should wait until after 39 0/7 weeks gestation.

In a large cohort of *planned term deliveries* (defined as deliveries not initiated by labor or ruptured membranes) during a 3-month period in 27 hospitals across the United States NICU admission rates were higher among neonates delivered in the early-term period. A comparison of NICU admission rates for neonates delivered at 37 weeks of gestation or 38 weeks of gestation with those for neonates delivered at 39 weeks of gestation revealed that 31% of 17,794 deliveries had no medical indication. Admission to the NICU, which can be dependent on a variety of factors, was required for 17.8% of infants delivered without medical indication at 37 weeks of gestation and for 8% delivered without medical indication at 38 weeks of gestation, compared with 4.6% of infants delivered at 39 weeks of gestation or beyond (P<.001 for deliveries at 38 weeks and 39 weeks of gestation).

Another large study found that although the rates of meconium aspiration were lower among neonates delivered at 37 weeks of gestation (adjusted OR, 0.62; 95% CI, 0.52–0.74) and 38 weeks of gestation (adjusted OR, 0.70; 95% CI, 0.62–0.79) compared with neonates delivered at 39 weeks of gestation, the rates of hyaline membrane disease were higher at 37 weeks of gestation (adjusted OR, 3.12; 95% CI, 2.90–3.38) and 38 weeks of gestation (adjusted OR, 1.30; 95% CI, 1.19–1.43).

When these two etiologies of pulmonary disease were examined as the combined metric of need for neonatal ventilation, the rates of disease were increased at both 37 weeks of gestation (adjusted OR, 2.02; 95% CI, 1.88–2.18) and 38 weeks of gestation (adjusted OR, 1.15; 95% CI, 1.08–1.23). Additionally, in this study, the risk of a 5-minute Apgar score less than 7 decreased from 1.01% at 37 weeks of gestation to 0.69% at 38 weeks of gestation and 0.61% at 39 weeks of gestation (P<.001). Alternatively, the risk of birth weight greater than 4,000 g increased from 2.0% at 37 weeks of gestation to 4.6% at 38 weeks of gestation and 7.9% at 39 weeks of gestation (P<.001).

Mortality rates are also higher among neonates and infants delivered during the early-term period compared with those delivered at full term. Using 39 weeks of gestation as the reference group, the relative risk of neo-natal mortality is 2.3 per 1000 live births (95% CI, 2.1–2.6) at 37 weeks of gestation and 1.4 (95% CI, 1.3–1.5) at 38 weeks of gestation. Mortality rates are also significantly higher among infants delivered at 37 weeks of gestation and 38 weeks of gestation compared with those delivered at 39 weeks of gestation. These increased mortality rates need to be balanced against the ongoing risk of stillbirth from week to week in the early-term pregnancy. In one recent study that compared the risk of neonatal mortality at a given week of gestation to the risk of expectant management, including stillbirth and neonatal mortality at the next week of gestation, there was an increased risk of mortality from delivery at 37 weeks of gestation (14.4 per 10,000 live births) compared with expectant management up to 38 weeks of gestation (12.6 per 10,000 live births, P<.05). At 38 weeks of gestation, the risk of mortality was 10.5 per 10,000 live births compared with 11.6 per 10,000 live births from expectant management up to 39 weeks of gestation. This risk difference of 1.1 per 10,000 pregnancies reached statistical significance (95% CI, 0.03–2.18 per 10,000 deliveries), but would require 9,042 deliveries at 38 weeks of gestation to prevent one death.

Table 1. Neonatal and Infant Mortality Rates Associated With Late-Preterm and Early-Term Deliveries

Gestational Age (wk)	Neonatal Mortality Rate (Per 1,000 Live Births)	Relative Risk (95% CI)	Infant Mortality Rate (Per 1,000 Live Births)	Relative Risk (95% CI)
34*	7.1*	9.5 (8.4-10.8)	11.8	5.4 (4.9-5.9)
35*	4.8	6.4 (5.6-7.2)	8.6	3.9 (3.6-4.3)
36*	2.8	3.7 (3.3-4.2)	5.7	2.6 (2.4-2.8)

37*	1.7	2.3 (2.1-2.6)	4.1	1.9 (1.8-2.0)
38*	1.0	1.4 (1.3-1.5)	2.7	1.2 (1.2-1.3)
39*	0.8	1.00†	2.2	1.00†
40*	0.8	1.0 (0.9-1.1)	2.1	0.9 (0.9-1.0)

Abbreviation: CI, confidence interval.
P<.001
†Reference group
Data from Reddy UM, Ko CW, Raju TN, Willinger M. Delivery indications at late-preterm gestations and infant mortality rates in the United States. Pediatrics 2009;124:234–40.

Policies restricting elective labor induction reduce time from admission to delivery, as well as reduce Cesarean delivery rates. A policy that allowed elective inductions for pregnant women who had a history of a prior successful vaginal delivery, had a favorable cervix, and were at least 39 weeks and 0/7 days gestation resulted in improved outcomes as compared to those inductions who did not meet the criteria. The average time from induction to delivery decreased from 17 to 11 hours, the Cesarean rate dropped from 16% to 7% and there were 1/3 fewer NICU admissions in the term induction group. It is felt that the Cesarean rate decreased due to a favorable cervix allowing progression of labor.

Prevention of Nonmedically Indicated Early-Term Deliveries

Implementation of a policy to decrease the rate of non-medically indicated deliveries before 39 weeks of gestation has been found to both decrease the numbers of these deliveries and improve neonatal outcomes. Clark and colleagues examined the implementation of three approaches to this issue: 1) a hard-stop policy, which prohibited non-medically indicated deliveries at the hospital level; 2) a soft-stop policy, in which health care providers agreed not to perform nonmedically indicated deliveries before 39 weeks of gestation; and 3) an education program that informed health care providers about the risks associated with delivery before 39 weeks of gestation. Overall, these approaches were able to demonstrate more than a 50% reduction in the rate of non-medically indicated early-term deliveries, regardless of the policy used. However, the reduction was the greatest in the hard-stop policy group, with a reduction from 8.2% to 1.7% (P=.007); slightly less in

the soft-stop policy group, with a reduction from 8.4% to 3.3% (P=.025), and least in the educational approach group, with a reduction from 10.9% to 6.0% (P=.135), which was not statistically significant.

In a parallel effort, the Ohio Perinatal Quality Collaborative chose to focus on the reduction of non-medically indicated deliveries at 36 0/7–38 6/7 weeks of gestation. Twenty hospitals in Ohio were enrolled in the study, and a range of approaches were provided to reduce non-medically indicated deliveries, including improved determination of gestational age, usage of the ACOG's criteria for indication for delivery, education of patients and health care providers regarding these indications and the risks of non-medically indicated delivery before 39 weeks of gestation, and measurement of the outcome of scheduled delivery without a documented indication. The researchers reported a reduction in the rate of non-medically indicated deliveries at 36 0/7–38 6/7 weeks of gestation from 13% to 8% (P=.003).

Another more recent study examined the effects of a policy to reduce the rate of non-medically indicated deliveries before 39 weeks of gestation similar to the hard-stop policy previously described. After implementation of this policy, the overall rate of deliveries at 37 weeks of gestation or 38 weeks of gestation decreased from 33.1% to 26.4% (P<.001). In addition, the rate of NICU admission for neonates delivered at term decreased from 9.3% to 8.6% (P=.04). However, there also was a statistically significant increase in the rate of stillbirth at 37 weeks of gestation or 38 weeks of gestation, from 2.5 per 10,000 births to 9.1 per 10,000 births (P=.032). Additionally, there was an 11% increase in odds of birth weight greater than 4,000 g (adjusted OR 1.11; 95% CI, 1.01–1.22).

These programs demonstrate that a reduction in non-medically indicated early-term and late-preterm deliveries can be achieved. However, to decrease the overall rate of perinatal morbidity and mortality before 39 weeks of gestation, additional steps beyond education and policy changes are needed.

Summary

Although there are specific indications for delivery before 39 weeks of gestation, a non-medically indicated early-term delivery is not appropriate. For certain medical conditions, available data and expert opinion support optimal timing of delivery in the late-preterm or early-term period for improved neonatal and infant outcomes. However, for non-medically indicated early-term deliveries, such an improvement has not been demonstrated. In fact, there are greater reported rates of morbidity and mortality among neonates and infants delivered during the early-term period compared with

those delivered at 39 weeks and 40 weeks of gestation. The differences between 37 weeks of gestation and 39 weeks of gestation are consistent, larger, and statistically significant across multiple studies. Even comparing neonates and infants delivered at 38 weeks of gestation with those delivered at 39 weeks of gestation there is still an increased (albeit clinically small) risk of adverse outcomes. The role of amniocentesis to determine pulmonary maturity is limited, and a mature fetal pulmonary maturity result does not ensure good neonatal outcomes and other morbidity. While education and policy changes lower non-medically indicated early-term deliveries, they are inadequate to completely eliminate the event. It is felt that a nonpayment policy for these not medically indicated deliveries will further serve to decrease their incidence.

Management decisions should balance the risks of pregnancy prolongation with the neonatal and infant risks associated with early-term delivery. Maternal-fetal-medicine consultation is encouraged in the evaluation of pregnancies considered for early-term delivery and in the assessment of the risks/benefits from such delivery.

References

1. World Health Organization. ICD-10: International statistical classification of diseases and related health problems, 10th revision. Volume 2. 2nd ed. Geneva: WHO; 2004. Available at: http://www.who.int/classifications/icd/ICD-10_2nd_ed_volume2.pdf. Retrieved August 12, 2013.
2. Tita AT, Landon MB, Spong CY, Lai Y, Leveno KJ, Varner MW, et al. Timing of elective repeat cesarean delivery at term and neonatal outcomes. Eunice Kennedy Shriver NICHD Maternal-Fetal Medicine Units Network. N Engl J Med 2009;360:111–20.
3. Reddy UM, Bettegowda VR, Dias T, Yamada-Kushnir T, Ko CW, Willinger M. Term pregnancy: a period of heterogeneous risk for infant mortality. Obstet Gynecol 2011;117:1279–87.
4. Nonmedically indicated early-term deliveries. Committee Opinion No. 561. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:911–5.
5. Martin JA, Hamilton BE, Sutton PD, Ventura SJ, et al. Births: Final data for 2006. National vital statistics reports; vol 57 no 7. Hyattsville, MD: National Center for Health Statistics. 2009
6. Goldenberg, RL, McCLure, EM, Bhattacharya, A, Groat, TD, Stahl, PJ, Women's Perceptions Regarding the Safety of Births at Various Gestational Ages. Obstetrics & Gynecology. Vol 114, No.6, December 2009.

7. Moore, LE, Rayburn WF. Elective induction of labor. Clin Obstet Gynecol 2006; 49: 698-704.
8. Definition of Term Pregnancy. Committee Opinion No. 579, American College of Obstetricians and Gynecologists. Obstet Gynecol 2013.
9. Shapiro-Mendoza CK et al. Effect of late-preterm birth and maternal medical conditions on newborn morbidity risk. *Pediatrics.* 2008;121:e223–e232
10. Consortium on Safe Labor, Hibbard JU, Wilkins I, Sun L, Gregory K, Haberman S, et al. Respiratory morbidity in late preterm births. JAMA 2010;304:419–25
11. Tita AT, Landon MB, Spong CY, Lai Y, Leveno KJ, Varner MW, et al. Timing of elective repeat cesarean delivery at term and neonatal outcomes. Eunice Kennedy Shriver NICHD Maternal-Fetal Medicine Units Network. N Engl J Med 2009;360:111–20.
12. Clark SL, Miller DD, Belfort MA, Dildy GA, Frye DK, Meyers JA. Neonatal and maternal outcomes associated with elective term delivery. Am J Obstet Gynecol 2009;200:156.e1–156.e4.
13. Cheng YW, Nicholson JM, Nakagawa S, Bruckner TA, Washington AE, Caughey AB. Perinatal outcomes in low-risk term pregnancies: do they differ by week of gestation? Am J Obstet Gynecol 2008;199:370.e1–370.e7.
14. Reddy UM, Ko CW, Raju TN, Willinger M. Delivery indications at late-preterm gestations and infant mortality rates in the United States. Pediatrics 2009;124:234–40.
15. Rosenstein MG, Cheng YW, Snowden JM, Nicholson JM, Caughey AB. Risk of stillbirth and infant death stratified by gestational age. Obstet Gynecol 2012;120:76–82.
16. Clark SL, Frye DR, Meyers JA, Belfort MA, Dildy GA, Kofford S, et al. Reduction in elective delivery at <39 weeks of gestation: comparative effectiveness of 3 approaches to change and the impact on neonatal intensive care admission and stillbirth. Am J Obstet Gynecol 2010;203:449.e1–449.e6.
17. Donovan EF, Lannon C, Bailit J, Rose B, Iams JD, Byczkowski T. A statewide initiative to reduce inappropriate scheduled births at 36(0/7)–38(6/7) weeks' gestation. Ohio Perinatal Quality Collaborative Writing Committee [published erratum appears in Am J Obstet Gynecol 2010;202:603]. Am J Obstet Gynecol 2010;202:243.e1–243.e8.
18. Ehrenthal DB, Hoffman MK, Jiang X, Ostrum G. Neonatal outcomes after implementation of guidelines limiting elective delivery before 39 weeks of gestation. Obstet Gynecol 2011;118:1047–55.
19. Healy, Andrew. Restricting Elective Inductions Reduces Cesareans. ACOG. May 2013

Elective Delivery of Pregnancy

Policy # 00422
Original Effective Date: 09/01/2014
Current Effective Date: 09/14/2020

Policy History

Original Effective Date: 09/01/2014
Current Effective Date: 09/14/2020
05/01/2014 Medical Policy Committee review
05/21/2014 Medical Policy Implementation Committee approval. New policy.
08/06/2015 Medical Policy Committee review
08/19/2015 Medical Policy Implementation Committee approval. No change to coverage.
08/04/2016 Medical Policy Committee review
08/17/2016 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
08/03/2017 Medical Policy Committee review
08/23/2017 Medical Policy Implementation Committee approval. No change to coverage.
08/09/2018 Medical Policy Committee review
08/15/2018 Medical Policy Implementation Committee approval. No change to coverage.
08/01/2019 Medical Policy Committee review
08/14/2019 Medical Policy Implementation Committee approval. No change to coverage.
08/06/2020 Medical Policy Committee review
08/12/2020 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 08/2021

*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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.