Medical Policy

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Procalcitonin Testing (PCT)

Description/Background

Identifying patients with bacterial infection and sepsis is a major challenge in emergency departments and critical care units, where mortality from sepsis remains high due to delayed diagnosis and treatment. Procalcitonin (PCT) is proposed as a marker for the diagnosis of clinically relevant bacterial infections and sepsis.

In healthy people, PCT is produced in the C cells of the thyroid gland and is a precursor for the hormone calcitonin. It normally is not found in the serum of healthy people. However, bacterial infections cause PCT to be produced by almost every organ of the body, resulting in a rapid rise of PCT levels in the blood. The level of PCT in the blood is a reflection of the severity of bacterial infection, ranging from slightly elevated concentrations in infections with minor systemic inflammatory response to very high values in cases of severe sepsis and septic shock. Procalcitonin levels decrease rapidly once an infection is under control.

Assays to determine the concentration of procalcitonin in serum and plasma are intended to be used in conjunction with other laboratory findings and clinical assessments. These findings aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis or septic shock

Regulatory Status

The U.S. Food and Drug Administration (FDA) has cleared for marketing through the 510(k) process the BRAHMS PCT sensitive KRYPTOR (Brahms USA, Inc., Annapolis, MD), the VIDAS BRAHMS PCT (bioMerieux, Inc., Hazelwood, MO), and the BRAHMS PCT LIA (BRAHMS Diagnostica, LLC, Tracys Landing, MD) quantitative assays to determine the concentration of PCT in serum and plasma. These devices utilize different technologies and instruments to obtain results but have a similar indication for use, which is to aid in the

assessment of risk progression to severe sepsis and septic shock in critically ill patients on the first day of admission to ICU. The devices are intended to be used in conjunction with other laboratory findings and clinical assessments to determine whether an infection is bacterial or viral, enabling the treating physician to avoid the unnecessary use of antibiotics.

The BRAHMS KRYPTOR® uses TRACE (Time Resolved Amplified Cryptate Emission) technology, based on a non-radiative transfer of energy. The VIDAS® B·R·A·H·M·S PCT test uses ELFA (Enzyme Linked Fluorescent Assay) technology which is based on a one-step immunoassay sandwich method and a final fluorescent detection step. Finally, the BRAHMS PCT LIA assay uses a "sandwich" type luminescence immunoassay and a coated-tube technique.

Medical Policy Statement

The safety and effectiveness of procalcitonin testing (PCT) for confirmation and monitoring of bacterial infections and sepsis in initiating or discontinuing antibiotics in specified patient populations have been established.

Inclusionary and Exclusionary Guidelines

Inclusions:
For use in the adult and pediatric population in the inpatient/emergency department setting for the following conditions:

- For the use in individuals with lower respiratory tract infections (e.g. pneumonia) for initiating and/or discontinuing antibiotic therapy **OR**
- For the use in critically ill individuals with sepsis as a guidance for discontinuation of antibiotic therapy.

Exclusions:
The use of procalcitonin testing for the following conditions is experimental/investigational because of insufficient evidence of its effectiveness (Note: This is not an all-inclusive list).
These indications include the diagnoses of:

- Surgical infections (including monitoring of the infection);
- Appendicitis;
- Chronic renal insufficiency;
- Infective endocarditis;
- Non-alcoholic fatty liver disease;
- Parapneumonic pleural effusions;
- Spontaneous bacterial peritonitis;
- Pancreatitis;
- Pyelonephritis

It is also considered experimental/investigational for:

- Measuring the differentiation of infection from other inflammatory complications following stem cell transplantation
- Predicting outcomes in persons with acute coronary syndrome.
- Prediction of neurological deficits following carotid endarterectomy

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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

84145

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Many markers have been evaluated as diagnostic indicators of bacterial infections and sepsis. Procalcitonin (PCT) and C-reactive protein (CRP) are two of these indicators. In a meta-analysis by Simon et al. (2004), PCT levels were found to be more accurate markers for bacterial infection than CRP when differentiating bacterial infections from noninfective causes of inflammation and in differentiating bacterial from viral infections.

Contradictory documentation in publications finds concerns in the prognostic and diagnostic utility of PCT. Interpretation is difficult due to varied patient characteristics and clinical settings vary markedly. High PCT commonly occurs in infection and may be elevated in some noninfectious conditions. The test in and of itself is not a specific indicator of either infection or sepsis.

Procalcitonin as a marker of sepsis in ICU patients and hospitalized patients with respiratory tract infections:

In 2007 Rau et al., when performing an international multicenter study, found procalcitonin monitoring to be a reliable approach in assessing septic multiorgan dysfunction syndrome (MODS) and overall prognosis in secondary peritonitis. This was a prospective, international, multicenter inception cohort study. Eighty-two patients with intraoperatively proven secondary peritonitis were enrolled within 96 hours of the onset of symptoms of symptoms of probable sepsis. Procalcitonin and the laboratory marker C-reactive protein (CRP) were prospectively assessed and monitored for a maximum of 21 consecutive days. Procalcitonin concentrations were most closely correlated with the development of septic multiorgan dysfunction syndrome (MODS), with peak levels occurring early after symptom onset or during the immediate postoperative course. No such correlation was observed for CRP. The authors concluded that procalcitonin monitoring is a fast and reliable approach to assessing septic MODS and overall prognosis in secondary peritonitis. Procalcitonin meets the demands of a readily available biochemical marker under clinical routine and emergency conditions. This test may indicate which patients are likely to develop clinically relevant complications that would require systemic antibiotics. Further evaluation is needed to evaluate the effectiveness of the test for other various medical conditions and treatment sites.

In a randomized trial by Nobre, et al. in 2008, the use of procalcitonin testing to shorten antibiotic treatment duration in septic patients suggested that serial PCT measurements may

allow for reducing antibiotic treatment in patients with severe sepsis and septic shock without adverse outcomes. In patients randomly assigned to the intervention group, antibiotics were stopped when PCT levels had decreased 90% or more from the initial value (if clinicians agreed) but not before Day 3 (if baseline PCT levels were <1 μg/L or Day *5* (if baseline PCT levels were >1 μg/L). In control patients, clinicians decided on the duration of antibiotic therapy based on empirical rules. Patients assigned to the PCT group had 3.5 day shorter median duration of antibiotic therapy for the first episode of Infection than control subjects (intention-to-treat, n = 79, *P* = 0.15). In patients In whom a decision could be taken based on serial PCT measurements, PCT guidance resulted in a 4-day reduction in the duration of antibiotic therapy (per protocol, n = 68, *P* = 0.003) and a smaller overall antibiotic exposure (P = 0.0002). A similar mortality and recurrence of the primary Infection were observed in PCT and control groups. A 2-day shorter intensive care unit stay was also observed in patients assigned to the PCT group (P=0.03). *Conclusions*: An algorithm based on serial PCT measurements allows more judicious antibiotic use in patients with severe sepsis and septic shock hospitalized in the ICU by reducing antibiotic exposure and lengths of hospital and ICU stay. No difference in 28-day mortality, clinical cure, and infection relapse rates was observed between patients treated according to PCT guidance and patients managed according to standard practice. A multicenter trial enrolling a large number of patients with severe sepsis and septic shock to test the PCT guidance protocol and its effect on ICU length of stay would be desirable to validate the data. In 2008, Becker, et al. performed a review of medical literature regarding the use of PCT as a marker of severe systemic inflammation, infection and sepsis. Literature was reviewed from 1965 through 2007, and included manual cross-referencing. (2) Available clinical and other patient data from these sources were reviewed, including any data relating to precipitating factors, clinical findings, associated illnesses, and patient outcome. Published data concerning sensitivity, specificity, and reproducibility of PCT assays were reviewed, Based on the available data, measurement of serum PCT has was shown to have definite use as a marker of severe systemic inflammation, infection and sepsis. However, attempts at meta-analyses were greatly compromised by the divergent circumstances of reported studies and by the sparsity and different timing of the PCT assays. At the time of this study, the most commonly applied assay (i.e., LUMitest) was insufficiently sensitive to detect potentially important mild elevations or trends.

Charles et al. (2009) conducted an observational cohort study examining the use of PCT as a way to assess the clinical efficacy of empirical antibiotic therapy in the early diagnosis of nosocomial infection in the ICU. The study included 180 patients with sepsis. Procalcitonin level was obtained daily over a 4-day period following the onset of sepsis. Appropriateness of the empirical antibiotic therapy and the overall survival were associated with a greater decline in PCT between day 2 and 3. The authors concluded the PCT monitoring could be helpful in the early diagnosis of nosocomial infection in the ICU. They also noted that additional studies are needed to determine the utility of daily PCT monitoring with clinical assessment in early management of sepsis.

In 2009, Rowther et al., reported on a prospective case control study comparing the results of a polymerase chain reaction (PCR) and PCT with blood culture in ICU patients suspected of having septicemia. There were 90 patients, 60 of which met the criteria for sepsis. Compared with blood culture as the gold standard, the sensitivity, specificity, and positive- and negative-predictive values for PCR were 100 %, 43.33 %, 46.87 %, and 100 %, respectively, and for PCT were 100 %, 61.66 %, 56.6 %, and 100 %, respectively. The average times required to produce a final result were as follows: PCR, 10 hrs; blood culture, 33 hrs; PCT, 45 mins. Although PCR and PCT appeared to be useful as rapid tests for detecting septicemia,

but compared with blood culture, which is deemed the gold standard, PCR and PCT lacked specificity.

Hochreiter et al., 2009 conducted a study investigating the clinical usefulness of PCT for guiding antibiotic therapy in surgical intensive care patients. Study participants included 110 surgical intensive care patients on antibiotic therapy after confirmed or high-grade suspected infections. In 57 patients, antibiotic therapy was guided by daily PCT levels and clinical assessment with appropriate adjustments to the medication. There were 53 patients in the control group that received a standard duration of antibiotic therapy over eight days. In the PCT group, the duration of antibiotic therapy was shorter than the control group (5.9 +/- 1.7 versus 7.9 +/- 0.5 days, *P* <.001) however, there were no negative effects on clinical outcome. The authors concluded that PCT could be used in addition to clinical assessment to guide the duration of antibiotic therapy in surgical intensive care patients. This may contribute to an optimized antibiotic regimen with beneficial effects on microbial resistance and costs in intensive care medicine.

Giamarellos-Bourboulis, et al., 2011 reported on the results of a prospective multicenter observational study exploring the role of procalcitonin in predicting the outcome of sepsis. The goal of this study was to establish thresholds of PCT that could differentiate risk of death separately for individuals who present with sepsis versus those who develop sepsis after ICU admission. There were 1156 hospitalized patients in this study, 234 of which were in the ICU when sepsis presented. Among patients outside the ICU, mortality was 8% in those with a PCT value $\leq$ 0.12 ng/mL but 19.9% in those with PCT >0.12 ng/mL. For those patients whose sepsis presented in the ICU, mortality was 25.6% in those with PCT $\leq$.85 ng/mL but 45.3% in those with PCT >.85 ng/mL. The authors concluded that establishing PCT cut-off values for predicting the outcome of sepsis could be of value in identifying patients who might benefit from ICU admission.

Procalcitonin measurements in non-sepsis conditions:

Multiple studies have been done and literature written studying the usefulness of procalcitonin testing for diagnosing various conditions, including surgical infections, appendicitis, chronic renal insufficiency, infective endocarditis, infections following stem cell transplantation, examining fevers of unknown origin in infants, etc. Much further study needs to be done regarding the use of PCT for these patients. However, for the initiation and discontinuation of antibiotic therapy in persons already in the intensive care unit and for persons with respiratory tract infections already in the hospital setting, PCT testing appears to reduce antibiotic prescription rates and duration of use.

Mommertz and co-workers (2009) stated that the outcome of carotid endarterectomy (CEA) is defined by the mortality rate and the neurological outcome due to cerebral ischemia. The authors assessed the role of the acute phase protein PCT as a predictor for neurological deficits following carotid endarterectomy. A total of 55 patients with high-grade stenosis of the internal carotid artery and inter-disciplinary consensus for endarterectomy were followed. Neurological examination was performed before and after the procedure to analyze peri-operative neurological deficits. Blood samples were obtained before and after CEA and PCT was analyzed in 55 consecutive patients (65.5 % symptomatic/34.5 % asymptomatic). No peri-operative or in-hospital death was observed. Major complications did not occur, 2 patients suffered from bleeding requiring surgical intervention and 1 patient had a temporary peripheral facial nerve lesion. Post-operative neurological examination revealed no new deficit, there was no significant change of PCT (level pre- and post-CEA (the mean pre-operative PCT was 0.25 ng/ml [SD 0.78, min = 0.1, max = 4.3]; the mean post-operative PCT

was 0.11 ng/ml [SD 0.06, min = 0.1, max = 0.5]). There was no association found between peri-operative neurological deficit and PCT. The authors concluded that these findings demonstrate that there is still insufficient evidence to recommend PCT measurement as a predictor for peri-operative neurological deficit during CEA.

In a review on the use of PCT in the diagnosis and monitoring of post-op infections, Zielinska-Borkowska et al (2009) stated that the PCT level assay enables the detection of a developing infection already in the latent stage, before characteristic clinical symptoms appear. However, additional research needs to be done to determine the accurate diagnostic value and the clinical application of the PCT level as a marker of infection.

Sand et al (2009) examined if PCT levels in the serum of patients with acute appendicitis have any diagnostic value. This prospective study included 103 patients who received an appendectomy, based on the clinical diagnosis of acute appendicitis in a surgical department of an academic teaching hospital in Germany or in a county hospital in Spain. White blood cell count (WBC), CRP and PCT values were determined pre-operatively. All appendectomy specimens were sent for routine histopathological evaluation. Based on this information, the patients were assigned to 1 of 5 groups that reflected the severity of the appendicitis. Of the 103 patients who were included in the study, 98 had appendicitis. Fourteen (14.3 %) showed an increase in PCT values. Of those 14, 4 had a serum PCT greater than 0.5 ng/ml, 9 had a PCT value greater than 2 to 10 ng/ml and 1 had a PCT value greater than 10 ng/ml. The sensitivity of PCT was calculated to be 0.14. The mean WBC value was 13.0/nl (+/- 5.2, range of 3.4 to 31), and for CRP it was 8.8 mg/dl (+/- 13, range of 0 to 60.2). The values of CRP, WBC and PCT increased with the severity of the appendicitis. The authors concluded that although PCT is potentially increased in rare cases of severe inflammation and after appendiceal perforation or gangrenous appendicitis, it has a remarkably low sensitivity. This low sensitivity prohibits its routine use for the diagnosis of appendicitis.

In 2009, Oruc et al. studied the diagnostic and discriminative role of serum PCT and CRP in non-alcoholic fatty liver disease (NAFLD). Fifty patients with NAFLD and 50 healthy controls were included to the study. Liver function tests were measured, body mass index was calculated, and insulin resistance was determined by using a homeostasis model assessment (HOMA-IR). Ultrasound evaluation was performed for each subject. Serum CRP was measured with nephelometric method; and serum PCT was measured with Kryptor based system. Results: Serum PCT levels were similar in steatohepatitis (n = 20) and simple steatosis (n = 27) patients, and were not different than the control group (0.06 +/- 0.01, 0.04 +/- 0.01 versus 0.06 +/- 0.01 ng/ml, respectively). Serum CRP levels were significantly higher in simple steatosis, and steatohepatitis groups compared to healthy controls (7.5 +/- 1.6 and 5.2 +/- 2.5 versus 2.9 +/- 0.5 mg/dl, respectively $p < .01$). C-reactive protein could not differentiate steatohepatitis from simple steatosis. In addition, 3 patients with focal fatty liver disease had normal serum CRP levels. Conclusion: Serum PCT was within normal ranges in patients with simple steatosis or steatohepatitis and has no diagnostic value. Serum CRP level was increased in NAFLD compared to controls; CRP can be used as an additional marker for diagnosis of NAFLD but it has no value in discrimination of steatohepatitis from simple steatosis.

In 2010, Ataoglu et al investigated clinical consequences of increased PCT levels in early atherosclerosis, which may lead to acute coronary syndrome. Consecutive patients who presented at the Coronary Care Unit of Haseki Training and Research Hospital (Fatih, Istanbul, Turkey) with a diagnosis of acute coronary syndrome (ACS) between September and November 2007 were enrolled in the study. The primary endpoints were in-hospital and 6-

month mortality. Multiple blood samples for measurement of PCT were taken at admission and at 48 h post-admission. Seventy-seven patients with a diagnosis of ACS were enrolled in the study. Of these, 29 patients had non-ST-elevation MI, 34 had ST elevation MI and 14 had unstable angina pectoris. The mean ± SD age of the patients was 61.4 ± 13.99 years and 19 were women. Five patients (two women) died during hospitalization, and 9 patients died during the 6 months of follow-up. The PCT levels at 48 h post-admission in the nine patients (five women) who died during the 6 months of follow-up were significantly higher compared with the surviving group. Fibrinogen, hs-CRP, glucose, electrolytes, lipid profile, white blood cell and platelet counts were similar in the patients who died within the 6-month follow-up period compared with those who survived. In this small group of ACS patients, it was found that PCT levels ≥ 0.05 ng/ml within 48 h after hospital admission might predict a high risk of mortality within the following 6 months. The findings from this study suggested that an increase in PCT could identify a high-risk population with high in-hospital and 6-month all-cause mortality. The conclusion was that higher PCT levels at 48 h after admission might reflect an inflammatory state. The major limitation of this study was that it was not possible to predict the influence of therapeutic agents on PCT levels due to the small number of patients. Another limitation was that these patients did not have access to the preferred treatments for MI, such as primary stenting, due to the fact that the study clinic was a secondary center in a developing country. The course of MI in this setting may resemble sepsis as an inflammatory condition. Because of the small sample size, it was not possible to draw any firm conclusions about the clinical utility of PCT setting for patients with ACS.

An evidence-based care guideline for the management of fever of unknown origin in infants under 2 months of age, which was produced by the Cincinnati Children's Hospital Medical Center, indicates that the inclusion of measurements of CRP and PCT levels in a diagnostic evaluation of fever of uncertain source does not improve the confidence in ruling out serious bacterial infections.

The Pediatric Infectious Diseases Society and the Infectious Diseases Society of America's clinical practice guideline on the management of community acquired pneumonia in infants and children older than 3 months of age (Bradley et al, 2011) stated that acute-phase reactants (e.g., the erythrocyte sedimentation rate, CRP concentration, or serum PCT concentration) cannot be used as the sole determinant to differentiate viral and bacterial causes of community acquired pneumonia.

In 2012 Shomali and colleagues examined the role of PCT in non-neutropenic febrile cancer patients (NNCPs). Between July 2009 and July 2010, a total of 248 NNCPs with fever were studied. Procalcitonin was measured in plasma within 24 hours of fever onset and 4 to 7 days thereafter. The patients' clinical, microbiological, and radiological data were reviewed to make the diagnosis and were correlated with PCT levels. This study included 30 patients with blood-stream infection (BSI), 60 with localized bacterial infection, 141 with no documented infection, and 8 with tumor-related fever. Most patients (98 %) were inpatients or admitted to the hospital during the study. Patients with BSI had significantly higher PCT levels than did those with documented localized infections ($p = 0.048$) and no documented infection ($p = .011$). Procalcitonin levels were significantly higher in septic patients than in those without sepsis ($p = .012$). Patients with stage IV disease or metastasis had significantly higher baseline PCT levels than did those with early stages of cancer ($p < .05$). Procalcitonin levels dropped significantly in patients with bacterial infections in response to antibiotics ($p < .0001$). Conclusions: Baseline PCT levels are predictive of BSI and sepsis in NNCPs. They may be predictors of metastasis and advanced cancer. Subsequent decrease in PCT levels in

response to antibiotics is suggestive of bacterial infection. Larger trials are needed to confirm the results of this pilot study.

In 2012, Zou and colleagues performed a systematic review and meta-analysis of the diagnostic performance of pleural fluid PCT or CRP in differentiating parapneumonic effusion in patients with pleural effusion. These investigators searched the Embase, Medline, and Cochrane database in December 2011. Original studies that reported the diagnostic performance of PCT alone or compared with that of other biomarkers for differentiating the characteristics of pleural effusion were included. The authors concluded that the existing literature suggested that both pleural fluid and serum PCT tests have low sensitivity and specificity for differentiating parapneumonic effusion from other etiologies of pleural effusion. Compared with PCT, serum CRP has higher specificity and a higher positive likelihood ratio, and thus, it has a higher rule-in value than PCT.

In 2013, Lyu and associates conducted a systematic review and meta-analysis of the performance of the PCT diagnostic test for identifying infectious complications after hematopoietic stem cell transplantation (HSCT). These investigators searched Embase, Medline, the Cochrane database, and reference lists of relevant articles, with no language restrictions, through December 2011. They selected original articles that reported diagnostic performance of PCT alone or compared with other biomarkers for identifying serious infections in HSCT recipients. The authors concluded that the pooled accuracy estimates of 6 different studies indicated only a moderate rule-out diagnostic value of both PCT and CRP in discriminating infection from other inflammatory complications following allogeneic HSCT.

In 2013, Lu et al. investigated the diagnostic value of PCT for patients with renal impairment and suspected systemic bacterial infection. Multiple databases were searched through December 2011 in order to evaluate the diagnostic performance of PCT among patients with renal impairment and suspected systemic bacterial infection. Two hundred one citations were reviewed, of which 7 diagnostic studies evaluated 803 patients and 255 bacterial infection episodes. There was no consistent evidence that PCT was more accurate than CRP test for the diagnosis of systemic infection among patients with renal impairment. Conclusion: Both PCT and CRP tests have poor sensitivity but acceptable specificity in diagnosing bacterial infection among patients with renal impairment. Given the poor negative likelihood ratio, its role as a rule-out test for systemic bacterial infection is questionable. Yu et al. (2013) systemically summarized the current evidence through September 2012 on the diagnostic value of PCT in identifying infective endocarditis (IE). They reported on the diagnostic performance of the use of PCT alone vs the use of other biomarkers to diagnose IE. They summarized test performance characteristics with the use of forest plots, hierarchical summary receiver operating characteristic curves, and bivariate random effects models. These researchers found 6 qualifying studies that included 1,006 episodes of suspected infection with 216 (21.5 %) confirmed IE episodes from 5 countries. The authors concluded that current evidence does not support the routine use of serum PCT or CRP to rule in or rule out IE in patients suspected to have IE.

Summary:

Serum procalcitonin levels have been identified as a promising biomarker that may assist in distinguishing bacterial infection from other causes of fever or sepsis (e.g., viral infections). The level of PCT in the serum is reportedly a reflection of the severity of bacterial infection, ranging from slightly elevated in infections with minor systemic inflammatory response to very high values in cases of severe sepsis and septic shock. Levels >2.0 ng/mL are highly

suggestive of systemic bacterial infection/sepsis or severe localized bacterial infection, such as severe pneumonia, meningitis, or peritonitis. Once an infection is under control, PCT levels decrease.

In view of the present emphasis on the overuse of antibiotics, other interventions to reduce antibiotic use, such as institution of antibiotic oversight programs and careful implementation of practice guidelines, practitioners have sought an alternative method of determining whether to initiate antibiotic therapy in the inpatient setting. This not only would reduce hospital costs but would also reduce the sequelae of antibiotic overuse. Numerous studies have shown that procalcitonin guidance can reduce antibiotic use when used to discontinue antibiotics in adult and pediatric critically ill patients with sepsis and to initiate or discontinue antibiotics in patients with lower respiratory tract infections. Populations for future research include immunocompromised patients, patients with other conditions (e.g., pregnancy, cystic fibrosis), and pediatric patients.

Government Regulations
National/Local:

There is no national or local coverage determination on this topic. There are fees for procedure code 84145 on the Clinical Diagnostic Laboratory Fee Schedule.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 21, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/09	12/1/08	10/13/08	Joint policy established.
9/1/10	6/15/10	6/15/10	Code update; deleted code 0194T, added 84145
9/1/12	6/12/12	6/19/12	Routine maintenance. No change in policy status.
7/1/14	4/8/14	4/15/14	Review of originally noncovered service. 84145 changed to established in the inpatient and outpatient setting for selected patients.
7/1/15	4/24/15	5/8/15	Routine maintenance Policy recommended for retirement
11/1/21	8/17/21		Unretire and updated JUMP policy from 2015 to replace IMP – Procalcitonin Testing policy.
11/1/22	8/16/22		Routine maintenance (ls)
11/1/23	8/23/23		• Added “in initiating or discontinuing antibiotics” to MPS. • Updated Inclusion statements: o For the use in individuals with lower respiratory tract infections (e.g. pneumonia) for initiating and/or discontinuing antibiotic therapy OR o For the use in critically ill individuals with sepsis as a guidance for discontinuation of antibiotic therapy. • Under Exclusions: Added Pancreatitis and Pyelonephritis. Vendor: Avalon Post JUMP updates: • PCT testing is used in peds/infants for evaluation of sepsis and that the statement in the exclusions regarding fever of uncertain source in infants would

			be confusing, therefore the statement: the evaluation of fever of uncertain source in infants was removed from the Inclusionary and Exclusionary Guidelines section under E/I. • Updated MPS to read: The safety and effectiveness of procalcitonin testing (PCT) for confirmation and monitoring of bacterial infections and sepsis in initiating or discontinuing antibiotics in specified patient populations have been established. • Updated the below statement under Inclusions for clarity: o Inclusions: o For use in the adult and pediatric population in the inpatient/emergency department setting for the following conditions: • Updated summary statement on page 9 of the policy to reflect changes made to the MPS and Inclusions section of the policy above to read: Numerous studies have shown that procalcitonin guidance can reduce antibiotic use when used to discontinue antibiotics in adult and pediatric critically ill patients with sepsis and to initiate or discontinue antibiotics in patients with lower respiratory tract infections. (ky)
11/1/24	8/20/24		• Routine maintenance • Vendor: Avalon. (ky)

Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PROCALCITONIN TESTING (PCT)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; policy criteria apply.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.