Please return all correspondence to:

«TableStart:PATIENTINFO» «Facility_Description»

NPI: «Facility_NPI»

Tax ID: «Facility Tax ID»

PTAN: «PTAN»

«TableEnd:PATIENTINFO»

April 9, 2020

«TableStart:PAYERINFO»

«PAY_Payer_Address1»

«PAY_Payer_City», «PAY_Payer_State» «PAY_Payer_Zip_Code»

«TableEnd:PAYERINFO»

«TableStart:PATIENTINFO» «Salutation_Recipient»:

This is a request for «Appeal_Description» on «PAT_Full_Name»'s denied claim for services at «Facility». The following is a summary of the denial from «Prior_Reviewing_Agency», as well as substantiation of the ICD-10-CM codes that support the proper DRG assignment.

Beneficiary Name	«PAT_Full_Name»
Member ID or	«MEMBER ID»
HIC Number	WHENTEEN_IS
Claim Dates of Service	«Svc_From» - «Svc_To»
Reason(s) for Denial	Allegation: Lack of clinical documentation to support the
Keason(s) for Demai	inclusion of Sepsis as a valid diagnosis on the claim
Reimbursement Change	Reassignment of DRG specify original DRG number and
	description to DRG specify new DRG number and description
Principal or Secondary	ICD-10-CM A41.9 (Sepsis, Unspecified organism) OR
Diagnosis in Question	Specify if Other

Below are significant medical record entries pertaining to «PAT_Full_Name»'s diagnosis of Sepsis.

Interdisciplinary Documentation:

Please read the following directives in red, add appropriate documentation in the tables below, then delete all the instructions in red.

Cite pertinent excerpts in the tables below pertaining to the diagnosis:

If SIRS due to infection = Sepsis fits your patient, regardless of the DOS:

1. Cite pertinent excerpts pertaining to the diagnosis (elevated temperature, leukocytosis, hypoxia, abnormal breath sounds, mental status changes, confirmation by infectious

disease specialist, treatment with anti-infective, labs and x-rays). Note if anti-infectives were in use prior to admission.

- 2. <u>Note VS around the time of presentation that show any of the below criteria</u> (1st set of VS, VS shortly after presentation, VS at home or in a physician's office, or by EMS can also be used):
 - *Body temperature* $\geq 38^{\circ}C$ (100.4°F) or $\leq 36^{\circ}C$ (96.8°F)
 - $Tachycardia \ge 90 \ beats/min$
 - $Tachypnea \ge 20 \ breaths/min \ (or \ PaCO2 \le 32 \ mm \ Hg)$

If SOFA and/or qSOFA fits your patient (for DOS on or after 2/23/16)

1. For patients NOT in the ICU:

Suspected infection; at least 2 of the following 3 criteria: systolic hypotension \leq 100mmHg, tachypnea \geq 22/min, and/or altered mentation.

Also look for confirmation of the diagnosis by infectious disease specialist; treatment with anti-infective; labs and imaging. Note if anti-infectives were in use prior to admission.

2. For patients IN the ICU:

<u>Sepsis:</u> Suspected infection; at least 2 of the following: PaO2/FiO2 mmHg of \leq 400; Platelets \leq 150,000; Bilirubin \geq 1.2; MAP \leq 70 mmHg; need for dobutamine drip, dopamine drip, norepinephrine drip, or epinephrine drip; GCS \leq 14; Cr. \geq 1.2 and/or urine output \leq 500ml/d.

<u>Septic shock</u>: sepsis plus lactate greater than 2 mmol/L (>18mg/dL) in the absence of hypovolemia and vasopressor requirement to maintain a mean arterial pressure of 65mmHg or greater.

Note several times where the diagnosis is documented by a licensed provider.

Document Source & Date	Pertinent Information	Page(s)

Vital Signs/Measurements

Delete the criteria and rows that do not apply to your patient

Vital	Date(s)	Results	Reference Range of	Page(s)
Signs/Measurements			values that are	
			representative of	
			Sepsis	
Body temperature			$\geq 38^{\circ}\text{C} (100.4^{\circ}\text{F}) \text{ or }$	
			≤ 36°C (96.8°F)	
Heart Rate			≥ 90 beats/min	
Respiratory Rate			\geq 20 breaths/min (or	
			$PaCO2 \le 32 \text{ mm Hg}$	
OR				
Systolic Blood Pressure			<100 mmHg	
Respiratory Rate			>22/minute	
Sepsis: Mean Arterial			<70 mmHg	
Pressure (MAP)			_	
Glasgow Coma Scale			<14	
(GCS)				
Septic Shock: Mean			Vasopressors needed to	
Arterial Pressure (MAP)			keep MAP ≥65	
Urine Output			< 500 mL/d	

LaboratoryDelete the criteria and rows that do not apply to your patient

Test	Date(s)	Results	Reference Range of values that are representative of Sepsis	Page(s)
ABG - PaCO2			≤ 32 mm Hg	
WBC – Leukocytes			\geq 12 000 cells/ μ L or \leq 4000 cells/ μ L	
% Bands			>10%	
OR				
PaO2/FiO2			<400mmHg	
Platelets			<150	
Bilirubin			>1.2 mg/dL	
Creatinine			>1.2 mg/dL	
Lactate			> 2mmol/L (>18mg/dL)	

Radiology

Test	Date(s)	Findings	Page
Chest X-ray			
CT Scan			

Justification for Appeal

The arguments presented below justify the inclusion of sepsis as a valid diagnosis for the following reasons:

- 1. There is not consensus in the medical community as to what constitutes "Sepsis". The payer references material that appears to originate from The Third International Consensus Definitions for Sepsis and Septic Shock. As clearly shown in the Evidence Based Guideline section below, this information has not been endorsed by many members of the medical community. Thus, it remains only one possible piece of information that physicians may consider, or may decide not to consider, when evaluating and treating their patients. Physicians are not bound by one group's opinions as to what constitutes a certain diagnosis.
- 2. Several states (IL, NY, OH, WI) have instituted laws, regulations, or policies to improve sepsis prevention and early recognition (https://www.cdc.gov/hai/pdfs/sepsis/VS-Sepsis-Policy-FINAL.pdf). Because the state of New York implemented regulations in 2013 regarding early diagnosis and treatment of sepsis using the SIRS + Infection (Sepsis 2) criteria, the Greater New York Health Association confirmed in January 2019 that United Healthcare had written to both the New York State Department of Health and the New York State Department of Financial Services, stating that it would not implement Sepsis-3 criteria in its medical record audits in the state of New York. This underscores the continued need to recognize SIRS + Infection as appropriate diagnostic criteria for the early detection of sepsis.
- 3. The CDC recognizes and endorses the early detection and treatment of sepsis in order to reduce sepsis mortality (https://www.cdc.gov/sepsis/prevention-activities/index.html).
- 4. The use of SOFA criteria as defined in The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) is not helpful for early detection of patients with sepsis.
- 5. The patient's diagnosis was in fact documented in the medical record.
- 6. Inclusion of sepsis, on the billed claim, is in accordance with the Uniform Hospital Discharge Data Set (UHDDS) and ICD-10-CM Official Coding Guidelines, and AHA Coding Clinic Guidelines pertaining to the coding requirements for the diagnosis of

sepsis (see citations below). There is no disclosure indicating the payer's contract provisions vary from the Uniform Hospital Discharge Data Set (UHDDS) and ICD-10-CM Official Coding Guidelines.

7. Further, there is no disclosure regarding consultation with a coder or clinician who has the expertise to understand and apply these guidelines. Accordingly, disclosure of this information is requested. (Revise this reference as warranted.)

Coding References ICD-10 Coding References

Selection of Principal Diagnosis

ICD-10-CM Official Guidelines for Coding and Reporting

Effective October 1, 2015

Section II. Selection of Principal Diagnosis

The circumstances of inpatient admission always govern the selection of principal diagnosis. The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care."

H. Uncertain Diagnosis

If the diagnosis documented at the time of discharge is qualified as "probable", "suspected", "likely", "questionable", "possible", or "still to be ruled out", or other similar terms indicating uncertainty, code the condition as if it existed or was established. The bases for these guidelines are the diagnostic workup, arrangements for further workup or observation, and initial therapeutic approach that correspond most closely with the established diagnosis.

Reporting Additional Diagnoses

ICD-10-CM Official Guidelines for Coding and Reporting

Effective October 1, 2015

Section III. Reporting Additional Diagnoses

GENERAL RULES FOR OTHER (ADDITIONAL) DIAGNOSES

The UHDDS item #11-b defines Other Diagnoses as "all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of stay.

For reporting purposes the definition for "other diagnoses" is interpreted as additional conditions that affect patient care in terms of requiring:

- Clinical Evaluation; *MET as evidenced by*
- **or** Therapeutic Treatment; *MET as evidenced by*
- <u>or</u> Diagnostic Procedures; <u>MET as evidenced by</u>

- <u>or</u> Extended Length of Hospital Stay, *MET as evidenced by*
- <u>or</u> Increased Nursing Care and/or Monitoring. *MET as evidenced by*

<u>Please note that only ONE of the above criteria needs to be met in order to make the diagnosis</u> reportable ("codeable").

Sepsis, Severe Sepsis, and Septic Shock

ICD-10-CM Official Guidelines for Coding and Reporting

Effective October 1, 2015

Section I. Conventions, general coding guidelines and chapter specific guidelines

The conventions, general guidelines and chapter-specific guidelines are applicable to all health care settings unless otherwise indicated. The instructions and conventions of the classification take precedence over guidelines.

C. Chapter-Specific Coding Guidelines

In addition to general coding guidelines, there are guidelines for specific diagnoses and/or conditions in the classification. Unless otherwise indicated, these guidelines apply to all health care settings. Please refer to Section II for guidelines on the selection of principal diagnosis.

- 1. Chapter 1: Certain Infectious and Parasitic Diseases (A00-B99)
 - d. Sepsis, Severe Sepsis, and Septic Shock
 - 1) Coding of Sepsis and Severe Sepsis
 - (a) Sepsis

For a diagnosis of sepsis, assign the appropriate code for the underlying systemic infection. If the type of infection or causal organism is not further specified, assign code A41.9, Sepsis, unspecified organism.

A code from subcategory R65.2, Severe sepsis, should not be assigned unless severe sepsis or an associated acute organ dysfunction is documented.

(i) Negative or inconclusive blood cultures and sepsis Negative or inconclusive blood cultures do not preclude a diagnosis of sepsis in patients with clinical evidence of the condition; however, the provider should be queried.

(ii) Urosepsis

The term urosepsis is a nonspecific term. It is not to be considered synonymous with sepsis. It has no default code in

the Alphabetic Index. Should a provider use this term, he/she must be queried for clarification.

(iii) Sepsis with organ dysfunction

If a patient has sepsis and associated acute organ dysfunction or multiple organ dysfunction (MOD), follow the instructions for coding severe sepsis.

(iv) Acute organ dysfunction that is not clearly associated with the sepsis

If a patient has sepsis and an acute organ dysfunction, but the medical record documentation indicates that the acute organ dysfunction is related to a medical condition other than the sepsis, do not assign a code from subcategory R65.2, Severe sepsis; An acute organ dysfunction must be associated with the sepsis in order to assign the severe sepsis code. If the documentation is not clear as to whether an acute organ dysfunction is related to the sepsis or another medical condition, query the provider.

(b) Severe sepsis

The coding of severe sepsis requires a minimum of 2 codes: first a code for the underlying systemic infection, followed by a code from subcategory R65.2, Severe sepsis; If the causal organism is not documented, assign code A41.9, Sepsis, unspecified organism, for the infection. Additional code(s) for the associated acute organ dysfunction are also required.

Due to the complex nature of severe sepsis, some cases may require querying the provider prior to assignment of the codes.

2) Septic shock

(a) Septic shock generally refers to circulatory failure associated with severe sepsis, and therefore, it represents a type of acute organ dysfunction.

For cases of septic shock, the code for the systemic infection should be sequenced first, followed by code R65.21, Severe sepsis with septic shock or code T81.12, Postprocedural septic shock. Any additional codes for the other acute organ dysfunctions should also be assigned.

As noted in the sequencing instructions in the Tabular List, the code for septic shock cannot be assigned as a principal diagnosis.

3) Sequencing of severe sepsis

If severe sepsis is present on admission, and meets the definition of principal diagnosis, the underlying systemic infection should be assigned as principal diagnosis followed by the appropriate code from subcategory R65.2 as required by the sequencing rules in the Tabular List. A code from subcategory R65.2 can never be assigned as a principal diagnosis.

When severe sepsis develops during an encounter (it was not present on admission), the underlying systemic infection and the appropriate code from subcategory R65.2 should be assigned as secondary diagnoses.

Severe sepsis may be present on admission, but the diagnosis may not be confirmed until sometime after admission. If the documentation is not clear whether severe sepsis was present on admission, the provider should be queried.

4) Sepsis and severe sepsis with a localized infection

If the reason for admission is both sepsis or severe sepsis and a localized infection, such as pneumonia or cellulitis, a code(s) for the underlying systemic infection should be assigned first and the code for the localized infection should be assigned as a secondary diagnosis. If the patient has severe sepsis, a code from subcategory R65.2 should also be assigned as a secondary diagnosis. If the patient is admitted with a localized infection, such as pneumonia, and sepsis/ severe sepsis doesn't develop until after admission, the localized infection should be assigned first, followed by the appropriate sepsis/ severe sepsis codes.

****The below coding update is effective October 1, 2015 to October 1, 2018. Please remove if this encounter occurred after 10/1/2018.****

5) Sepsis due to a postprocedural infection

(a) Documentation of causal relationship

As with all postprocedural complications, code assignment is based on the provider's documentation of the relationship between the infection and the procedures.

(b) Sepsis due to a postprocedural infection

For such cases, the postprocedural infection code, such as T80.2, Infections following infusion, transfusion, and therapeutic injection, T81.4, Infection following a procedure, T88.0, Infection following immunization, or O86.0, Infection of obstetric surgical wound, should be coded first, followed by the code for the specific infection. If the patient has severe sepsis, the appropriate code from subcategory R65.2 should also be assigned with the additional code(s) for any acute organ dysfunction.

(c) Postprocedural infection and postprocedural septic shock

In cases where a postprocedural infection has occurred and has resulted in severe sepsis the code for the precipitating complication such as code T81.4, Infection following a procedure, or O86.0, Infection of obstetrical surgical wound should be coded first followed by code R65.20, Severe sepsis without septic shock. A code for the systemic infection should also be assigned.

If a postprocedural infection has resulted in postprocedural septic shock, the code for the precipitating complication such as code T81.4, Infection following a procedure, or O86.0, Infection of obstetrical surgical wound should be coded first followed by code T81.12-, Postprocedural septic shock. A code for the systemic infection should also be assigned.

****The below coding update is effective October 1, 2018. Please removed if this encounter occurred prior to 10/1/2018).****

5) Sepsis due to a postprocedural infection

(a) Documentation of causal relationship

As with all postprocedural complications, code assignment is based on the provider's documentation of the relationship between the infection and the procedures.

(b) Sepsis due to a postprocedural infection

For infections following a procedure, a code from T81.40 to T81.43, Infection following a procedure, or a code from O86.00 to O86.03, Infection of obstetric surgical wound, that identifies the site of the infection should be coded first, if known. Assign an additional code for sepsis following a procedure (T81.44) or sepsis following an obstetrical procedure (O86.04). Use an additional code to identify the infectious

agent. If the patient has severe sepsis, the appropriate code from subcategory R65.2 should also be assigned with the additional code(s) for any acute organ dysfunction.

For infections following infusion, transfusion, therapeutic injection, or immunization, a code from subcategory T80.2, Infections following infusion, transfusion, and therapeutic injection, or code T88.0-, Infection following immunization, should be coded first, followed by the code for the specific infection. If the patient has severe sepsis, the appropriate code from subcategory R65.2 should also be assigned, with the additional codes(s) for any acute organ dysfunction.

(c) Postprocedural infection and postprocedural septic shock

If a postprocedural infection has resulted in postprocedural septic shock, assign the codes indicated above for sepsis due to a postprocedural infection, followed by code T81.12-, Postprocedural septic shock. Do not assign code R65.21, Severe sepsis with septic shock. Additional code(s) should be assigned for any acute organ dysfunction.

6) Sepsis and severe sepsis associated with a noninfectious process (condition)

In some cases a noninfectious process (condition), such as trauma, may lead to an infection which can result in sepsis or severe sepsis. If sepsis or severe sepsis is documented as associated with a noninfectious condition, such as a burn or serious injury, and this condition meets the definition for principal diagnosis, the code for the noninfectious condition should be sequenced first, followed by the code for the resulting infection. If severe sepsis is present, a code from subcategory R65.2 should also be assigned with any associated organ dysfunction(s) codes. It is not necessary to assign a code from subcategory R65.1, Systemic inflammatory response syndrome (SIRS) of non-infectious origin, for these cases.

If the infection meets the definition of principal diagnosis, it should be sequenced before the non-infectious condition. When both the associated non-infectious condition and the infection meet the definition of principal diagnosis, either may be assigned as principal diagnosis.

Only one code from category R65, Symptoms and signs specifically associated with systemic inflammation and infection, should be assigned. Therefore, when a non-infectious condition leads to an infection resulting in severe sepsis, assign the appropriate code from subcategory R65.2, Severe sepsis. Do not additionally assign a code from subcategory R65.1, Systemic inflammatory response syndrome (SIRS) of noninfectious origin.

<u>Clarification: Code First Instructional Note</u> <u>Coding Clinic</u>, First Quarter 2016: Page 38;

Coding advice or code assignments contained in this issue effective with discharges March 18, 2016.

Question:

Some payers are denying claims when heart failure or sepsis codes are sequenced as the principal diagnosis because they are misinterpreting the "code first" note at categories I50, Heart failure, and A41, Other sepsis. They are denying the claim based on the belief that the conditions listed in the note are always sequenced first, even though the patient may not have any of the conditions listed. Could you please clarify the intent of the instructional note?

Answer:

The "code first" note means code first, if present. This instructional note is intended for conditions that have both an underlying etiology and manifestation, and indicates the proper sequencing order: etiology first, followed by the manifestation. However, this instructional note is only applied when the underlying conditions listed in the note are present. If these conditions are not present, the code first note is not applicable.

Sepsis Coding Issues

Coding Clinic, Third Quarter 2016: Page 8;

Coding advice or code assignments contained in this issue effective with discharges September 23, 2016.

The AHA Central Office on ICD-10-CM/PCS has received a number of inquiries about the appropriate coding of "viral sepsis". The following guidance has been developed to assist coders in classifying viral sepsis. Viral sepsis is a systemic infection caused by the presence of a virus in the blood. Although sepsis is most commonly caused by bacterial infection, it may also be caused by virus, fungi, and/or parasites. Assign code A41.89, Other specified sepsis, for a diagnosis of viral sepsis. Although codes in categories A30-A49 classify bacterial illnesses, ICD-10-CM does not provide a specific viral sepsis code, and A41.89 is the best available option. Code B97.89 should also be assigned as an additional code to provide further specificity and convey that the sepsis is due to a viral infection, when the specific type of viral infection is not documented. A code from subcategory R65.2, Severe sepsis, would not be assigned unless severe viral sepsis or an associated acute organ dysfunction is documented.

Question:

We have seen the recently issued consensus definitions for sepsis and septic shock. How and when will this affect the coding of sepsis and septic shock for ICD-10-CM? Will the Cooperating Parties be modifying the coding guidelines because of the new clinical definitions for sepsis?

Answer:

The coding guidelines are based on the ICD-10-CM classification as it exists today. Continue to code sepsis, severe sepsis and septic shock using the most current version of the ICD-10-CM classification and the ICD-10-CM Official Guidelines for Coding and Reporting. Code assignment is based on provider documentation (regardless of the clinical criteria the provider used to arrive at that diagnosis).

Diagnostic and Evidence Based Clinical References

Below are popular justifications related to standards of care relevant to this diagnosis. Please note that all citations may not be relevant to your patient. Inapplicable material should be deleted.

Source/Reference	Flynn, M.B. and Bridges, E. (2018). Managing Sepsis and Septic							
	Shock: Current Guidelines and Definitions (Recent updates							
	emphasize early recognition and prompt intervention). AJN, 118(2),							
	34-39. Retrieved from:							
	https://journals.lww.com/ajnonline/Pages/articleviewer.aspx?year=2018							
	&issue=02000&article=00022&type=Fulltext							
Evidence Based	SSC definitions for systemic inflammatory response syndrome							
Guideline/Practice	(SIRS) includes the presence of at least two of the following							
Guideline	clinical criteria:							
Recommendation	1. Temperature, $< 36^{\circ}\text{C} \text{ or} > 38.3^{\circ}\text{C}$							
	2. Heart rate, > 90 bpm							
	3. Respiratory rate, > 20 bpm, or PaCO2, < 32 mmHg							
	4. WBC count, < 4,000 mm3 or > 12,000 mm3 [p. 36]							
	• SSC definition for sepsis is defined by the presence of at least two							
	SIRS criteria and known or suspected infection. [p. 36]							
	• Severe sepsis SSC definition:							
	1. Sepsis-induced hypotension							
	2. SBP, < 90 mmHg							
	3. MAP, < 70 mmHg, or an SBP reduction of 40 mmHg from baseline							
	4. Serum lactate, > 2 mmol/L							
	5. Signs of organ dysfunction (acute oliguria, for example).							
	5. Signs of organ dysfunction (acute oliguria, for example). [p. 36]							
	 Shock SSC definition: Sepsis-induced hypotension that persists 							
	despite adequate fluid resuscitation and requires vasopressors to							
	support perfusion. [p. 36]							
Source/Reference	Levy, M.M., Evans, L.E and Rhodes, A. (2018). The Surviving Sepsis							
	Campaign Bundle: 2018 update. Intensive Care Med, 44(2018), 925-							
	928. Retrieved from:							
	http://stroke.ahajournals.org/content/44/6/1601.long							

Evidence Deced	The most immediate description of the grade
Evidence Based	• The most important change in the revision of the SSC bundles is
Guideline/Practice	that the 3-h and 6-h bundles have been combined into a single
Guideline Baseman detion	"hour-1 bundle" with the explicit intention of beginning
Recommendation	resuscitation and management immediately. [p. 925]
	Bundle elements recommendations:
	1. Measure lactate level. Re-measure if initial lactate is > 2 mmol/L
	2. Obtain blood cultures prior to administration of antibiotics
	3. Administer broad-spectrum antibiotics
	4. Rapidly administer 30 ml/kg crystalloid for hypotension or lactate ≥ 4 mmol/L
	5. Apply vasopressors if patient is hypotensive during or after fluid resuscitation to maintain MAP ≥ 65 mm Hg. [p. 926]
	• If initial lactate is elevated (> 2 mmol/L), it should be remeasured
	within 2–4 h to guide resuscitation to normalize lactate in patients
	within 2–4 if to guide resuscritation to normalize factate in patients with elevated lactate levels as a marker of tissue hypoperfusion.
	Cultures must be obtained before antibiotic administration to
	optimize the identification of pathogens and improve outcomes.
	[p. 926]
	For patients presenting with sepsis or septic shock empiric broad- appearum thereby should be started immediately with one or more
	spectrum therapy should be started immediately with one or more
	intravenous antimicrobials to cover all likely pathogens. [p. 926]
	Initial fluid resuscitation should begin immediately upon
	recognizing a patient with sepsis and/or hypotension and elevated
	lactate, and completed within 3 h of recognition. [p. 927]
Source/Reference	Cortes-Puch, I. & Hartog, C. (July 2016). Opening the Debate on the
	New Sepsis Definition. Change Is Not Necessarily Progress: Revision
	of the Sepsis Definition Should Be Based on New Scientific Insights.
	American Journal of Respiratory and Critical Care Medicine. As found
	on: http://www.atsjournals.org/doi/full/10.1164/rccm.201604-0734ED
Evidence Based	"Despitelimitations, the SIRS criteria have been practical and
Guideline/Practice	widely used for quality improvement initiatives (8/9) and
Guideline	awareness campaigns (10) to educate clinicians and the public
Recommendation	about the early signs and symptoms of sepsis and that delaying
	treatment can be lethal." [p.2]
	"There is currently no test or gold standard to identify patients
	with sepsisDetermining the diagnostic accuracy of a new or
	revised definition is not feasible without a gold standard to
	identify patients with the clinical syndrome." [p.2]
	"The decision to revise the definition should reflect unambiguous now developments in the field, gether then expect entition."
	new developments in the field, rather than expert opinion.
	Changes in the definition should be occasioned by true

	breakthroughs in scientific understand or clinical evidence, and not by changes in task force members, their inclinations, or new consensus procedures." [p.1] • "The new definition, requiring the presence of organ failure, may hinder general awareness of the importance of early recognition and treatment. Ideally, patients at risk for sepsis should be identified before organ dysfunction is established to prevent organ injury from occurring The revised definition will likely identify a sicker population and could potentially delay treatment of patients who might benefit from an early approach." [p.2] • "Early recognition and treatment of sepsis is currently accepted as a general principal, and has been deemed especially important in low and middle-income regions (11). However, the 2016 task force failed to include representatives from any of these regions where the underlying infections and the priorities for improving quality of care may differ from those in high-income regions. Some professional societies of emergency medicine and low and middle-income regions have already voiced this concern and have not endorsed this new definition (12, 13)." [p.2]
Source/Reference	Nguyen, H.B., Rivers, E., Abrahamian, F., Moran, G., Abraham, E. Trzeciak, STalan, D. (2006). Severe Sepsis and Septic Shock: Review of the Literature and Emergency Department Management Guidelines. Annals of Emergency Medicine. As found on: http://nuhem.com/emlinks/LLSA%20Articles%202008/Severe%20Sepsis%20and%20Septic%20Shock.pdf
Evidence Based Guideline/Practice Guideline Recommendation	 "Sepsis is defined as the presence or presumed presence of an infection accompanied by evidence of a systemic response called the systemic inflammatory response syndrome. Systemic inflammatory response syndrome is defined as the presence of 2 or more of the following: (1) temperature greater than 38°C (100.4°F) or less than 36°C (96.8°F); (2) pulse rate greater than 90 beats/min; (3) respiratory rate greater than 20 breaths/min (or PaCO2 less than 32 torr); and (4) WBC count greater than 12,000/mm³ or less than 4,000/mm³, or greater than 10% immature band forms." [p.3] "Severe sepsis is defined as the presence of sepsis and 1 or more organ dysfunctions. Organ dysfunction can be defined as acute lung injury; coagulation abnormalities; thrombocytopenia; altered mental status; renal, liver, or cardiac failure; or hypoperfusion with lactic acidosis. Septic shock is defined as the presence of sepsis and refractory hypotension, ie, systolic blood pressure less than 90 mm Hg, mean arterial pressure less than 65 mm Hg, or a decrease of 40 mm Hg in systolic blood pressure compared to

	baseline unresponsive to a crystalloid fluid challenge of 20 to 40 mL/kg. Bacteremia is the presence of viable bacteria in the blood and is found only in about 50% of cases of severe sepsis and septic shock, whereas 20% to 30% of patients will have no microbial cause identified from any source." [p.3] • "The presence of immunocompromising conditions and prosthetic devices such as intravenous lines, heart valves, and urinary catheters increases infection riskThe hallmark finding of infection is fever. General thresholds for abnormally high or low temperatures are based on studies of various populations and can vary among individuals and time of day (ie, temperatures tend to be lower in the early morning). The elderly and patients with myocardial dysfunction and shock tend to have lower temperatures than younger adults. Oral temperature above 37.2°C or 99.0°F (or rectal temperatures above 37.5°C or 99.5°F) should be considered a fever in the elderly. Temperature less than 36°C or 96.8°F is associated with the presence of severe infection. Also, some patients may present without fever, and develop fever during their evaluation or after resuscitation."[p.5]
Source/Reference	Singer, M., Deutschman, C.S., Seymour, C.W., Shankar-Hari, M., Annane, D., Bauer, MAngus, D.C. (2016). The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). <i>JAMA</i> . As found on: http://jama.jamanetwork.com/article.aspx?articleID=2492881
Evidence Based Guideline/Practice Guideline Recommendation	 "Sepsis should be defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. For clinical operationalization, organ dysfunction can be represented by an increase in the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score of 2 points or more, which is associated with an in-hospital mortality greater than 10%." [p.1] "Septic shock should be defined as a subset of sepsis in which particularly profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone. Patients with septic shock can be clinically identified by a vasopressor requirement to maintain a mean arterial pressure of 65mmHg or greater and serum lactate level greater than 2 mmol/L (>18mg/dL) in the absence of hypovolemia. This combination is associated with hospital mortality rates greater than 40%." [p.1] "In out-of-hospital, emergency department, or general hospital ward settings, adult patients with suspected infection can be rapidly identified as being more likely to have poor outcomes typical of sepsis if they have at least 2 of the following clinical

	criteria that together constitute a new bedside clinical score termed quickSOFA (qSOFA): respiratory rate of 22/min or greater, altered mentation, or systolic blood pressure of 100mmHg or less."[p.1]							
Source/Reference	Seymour, C.W., Liu, V.X., Iwashyna, T.J., Brunkhorst, F.M., Rea, T.D., Sherag, AAngus, D.C. (2016). Assessment of Clinical Criteria for Sepsis For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). <i>JAMA</i> . As found on: http://jama.jamanetwork.com/article.aspx?articleid=2492875							
Evidence Based Guideline/Practice Guideline Recommendation	 "For infected patients outside of the ICU, there is an increasing focus on early recognition of sepsisa simple model (qSOFA) uses 3 clinical variables, has no laboratory tests, and has a predictive validity outside of the ICU that is statistically greater than the SOFA score (P < .001)." [p.11] Quick Sequential [Sepsis-related] Organ Failure Assessment (qSOFA) score (range,0-3 points, with 1 point each for: systolic hypotension [≤100mmHg] tachypnea [≥22/min], or altered mentation).[p.1] "Among ICU encounters with suspected infection, the predictive validity for in-hospital mortality of SOFA was not significantly different than the more complex LODS but was statistically greater than SIRS and qSOFA, supporting its use in clinical criteria for sepsis." [p.12] 							
Source/Reference	Ferreira, F.L., Bota, D. P., Bross, A., Melot, C. & Vincent, J-L. (2001). Serial Evaluation of the SOFA Score to Predict Outcome in Critically Ill Patients. <i>JAMA</i> . As found on: http://jamanetwork.com/journals/jama/fullarticle/194262							
Evidence Based Guideline/Practice Guideline		Table 1. The Sequential Organ Failure Assessment (SOFA) Score*						
Recommendation	Respiratory Pao2/Fio2, mmHg	> 400	≤ 400	≤ 300	≤ 200 ₁	≤ 100 ₁		
	Coagulation Platelets x 103 μL ₂	> 150	≤ 150	≤ 100	≤ 50	≤20		
	Liver Bilirubin, mg/dl ₂	< 1.2	1.2 - 1.9	2.0 - 5.9	6.0 - 11.9	> 12.0		
	Cardiovascular Hypotension , Central nervous syste	No Hypo- tension	MAP < 70	$Dop \le 5$ or dob $(any dose)_3$	$\begin{aligned} &\text{Dop} > 5, \\ &\text{epi} \leq 0.1, \\ &\text{or norepi} \leq 0.1 \end{aligned}$	Dop > 15, epi > 0.1,or norepi >0.1 ₃		

Glasgow Coma Scale	15	13, 14	10 - 12	6-9	<6
Renal Creatinine, mg/dl or urine output, mL/d ₄	< 1.2	1.2 - 1.9	2.0 - 3.4	3.5 - 4.9 or < 500	> 5.0 or <200
*Norepi indicates norep fraction of inspired oxy 1 Values are with respir 2To convert bilirubin fr 3 Adrenergic agents adr 4 To convert creatinine	gen atory suppom mg/dl ministered	oort. to µmol/L, m for a least 1 h	ultiply by 17.1 our (doses giv	en are in μg/kg pe	•

Conclusion

«Facility» provided medically necessary services to «Patient_First» «Patient_Last» with the expectation that those services would be reimbursed according to the documentation in all UHDDS communications. «Facility» respectfully requests that you reconsider this claim and require payment to be made to «Facility» for the services provided to «Patient_First» «Patient_Last» in this case.

I appreciate your attention to this matter and invite you to contact me should you have any questions.

Respectfully,

Image_Signature

«Facility_Signature»

Submitted with the authority of the Provider,

Please return all correspondence to:

«Facility_Description»

NPI: «Facility_NPI»

Tax ID: «Facility_Tax_ID»

PTAN: «PTAN»

«TableEnd:PATIENTINFO»