Please return all correspondence to:

Memorial Medical Center
8600 LaSalle Rd. Suite 625
Towson, MD, 21286

NPI: XXXXXXXXXX
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June 29, 2019

Payer Health Care
Attn: Provider Appeals Unit
P.O. Box 497
Toledo, OH 43697-0497

Dear Reviewer:

This is a request for Redetermination on Jane Doe's denied claim for services at Memorial Medical Center. The following is a summary of the denial from Payer Health Care, as well as substantiation of the ICD-10-CM codes that support the proper DRG assignment.

Beneficiary Name	Jane Doe
Member ID or HIC Number	XXXXXXXXX
Claim Dates of Service	10/31/2018 - 11/02/2018
Reason(s) for Denial	Allegation: Lack of clinical documentation to support the inclusion of Sepsis and Acute Kidney Injury (AKI) as valid diagnoses on the claim
Reimbursement Change	Reassignment of DRG 872, Septicemia or Severe Sepsis W/O MV >96 Hours W/O MCC to DRG 153, Otitis Media and URI W/O MCC
Principal or Secondary Diagnosis in Question	ICD-10-CM Codes A41.9, Sepsis, Unspecified organism, as the principal diagnosis and N17.9, Acute Kidney Failure Unspecified, as a secondary diagnosis

ICD-10-CM Codes A41.9, Sepsis, Unspecified organism, as the principal diagnosis and N17.9, Acute Kidney Failure Unspecified, as a secondary diagnosis, were correctly assigned, resulting in DRG 872, Septicemia or Severe Sepsis W/O MV >96 Hours W/O MCC. Memorial Medical Center is requesting that the claim be processed for payment at this DRG, as originally submitted.

Below are significant medical record entries pertaining to Jane Doe's diagnoses of Sepsis and AKI.

Interdisciplinary Documentation:

Document Source & Date	Pertinent Information	Page(s)
ED Provider Note 10/31/18	Principal Diagnosis: **Sepsis** 69 yo presenting with **sepsis, sepsis** work up, likely 2/2 pneumonia, broad spectrum antibiotics, fluids, blood cultures, to be admitted.	152, 154
Physician Orders 10/31/18	Admit to inpatient level of care. Diagnosis: **Sepsis**	118
History and Physical 11/1/18	T 100.3, HR 105, RR 20 Azithromycin and ceftriaxone given **Admitted for sepsis** in setting of rhino/entero virus, **found to have AKI** **Problem:** Sepsis Plan: **febrile +tachycardia ->RVP(+)** -likely in setting of viral illness **- little PO intake x last 3 days** -s/p IVF resuscitation 2L NS -f/u blood cultures, check UA, procalcitonin -continue to monitor vitals **Problem: AKI (acute kidney injury)** Plan: **in setting of sepsis** **Baseline creatinine 0.8, today 1.3** **-check urine Na, creatinine, Urea and calculate FeUrea** **-?post obstructive, will hold oxybutynin** **-continue to trend serum Cr and BUN daily**	160 164 165
Physician Progress Note 11/1/18	**Admitted for sepsis** in setting of rhino/entero virus, **found to have AKI** **Problem: Sepsis** Plan: **febrile +tachycardia ->RVP(+)** -s/p IVF resuscitation 2L NS -f/u blood cultures, check UA, procalcitonin **Problem: AKI (acute kidney injury)** Plan: **in setting of sepsis** Cr appears to be resolving Problem: Hypertension Plan: **Holding home Lisinopril and Lasix in setting of sepsis and AKI**	192 193
Care Plan 11/1/18, 11/2/18	**Sepsis** signs and symptoms, Plan of Care ongoing, interventions implemented as appropriate	65, 69, 70
Physician Progress Note 11/2/18	**Problem: Sepsis** Plan: **febrile +tachycardia ->RVP(+)**	232

	-s/p IVF resuscitation 2L NS **Problem: AKI (acute kidney injury)** **Plan: in setting of sepsis** Problem: Hypertension Plan: **Holding home Lisinopril and Lasix in setting of sepsis and AKI**	233
Discharge Note 11/2/18	**Reason for Admission: Sepsis** **AKI, Cr 1.36, down trended to 1.02**	208

Vital Signs/Measurements

Vital Signs/Measurements	Date(s)	Results	Reference Range of values that are representative of Sepsis	Page(s)
Body temperature	10/31/18	**100.3 after IV Tylenol**	≥ 38°C (100.4°F) or ≤ 36°C (96.8°F)	62 45
Heart Rate	10/31/18	**105**	≥ 90 beats/min	61
Respiratory Rate	10/31/18	**20**	≥ 20 breaths/min (or PaCO2 ≤ 32 mm Hg)	61

Laboratory

Test	Date(s)	Results	Reference Range of values that are representative of Sepsis	Page(s)
Creatinine	10/31/18	**1.36**	>1.2 mg/dL	33

Test	Date(s)	Result	Reference Range	Page(s)
GFR	10/31/18 11/1/18 11/2/18	**53** **65** **75**	>60	33 28 26
Creatinine	Baseline 10/31/18 11/1/18 11/2/18	**0.8** **1.36** **1.15** **1.02**	0.5-1.3 mg/dl	165 33 28 26

Cardiology

Test	Date(s)	Findings	Page
EKG	10/31/18	**Abnormal EKG** **Sinus tachycardia** **Incomplete right bundle branch block**	40

		Inferior infarct, age undetermined Cannot rule out anterior infarct, age undetermined	

Justification for Appeal

The arguments presented below justify the inclusion of sepsis and Acute Kidney Injury AKI as a valid diagnoses 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. The criteria referred to by the reviewer are *not* required for the physician to diagnose the patient with sepsis. The physician clearly and consistently documented that the patient was admitted for sepsis. The physicians clearly determined that the patient's presentation could *not* be explained by a localized infection alone. The physician is *required* to utilize his/her *clinical judgment* and consider the patient's *entire* clinical picture when diagnosing the patient. Limiting the physician's ability to diagnose a patient to a list of criteria would be inappropriate.**

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. **Per JAMA** (see reference below):

Sepsis-3 definitions are *inconsistent* with the ICD-10-CM Official Guidelines for Coding and Reporting (OCG). Adherence to these guidelines when assigning diagnosis codes is *required* under the Health Insurance Portability and Accountability Act (HIPAA). While physicians may use a particular clinical definition or set of clinical criteria to establish a diagnosis, **the code is based on his/her documentation**, **not on a particular clinical definition or criteria.** In other words**, regardless of whether a physician uses the new clinical criteria for sepsis, the old criteria, his personal clinical judgment, or something else to decide a patient has sepsis (and document it as such), the code for sepsis is the same—as long as sepsis is documented, regardless of how the diagnosis was arrived at, the code for sepsis can be assigned.**

6. **As a term, Acute Kidney Injury (AKI) encompasses all stages of AKI** including Prerenal, Acute Renal Failure (ARF) and Acute Tubular Necrosis (ATN).

7. **There are many different clinical algorithms that purport to define AKI. Many of these are in use worldwide, however there is no American or International consensus statement deeming one to be superior or have more clinical validity than another**. **Consequently, it is up to the individual physician to determine which criteria are appropriate for the individual patient and circumstances**.

8. In this case, the diagnosis of AKI was entered into the medical record by the physicians responsible for the care of the patient. Further, the patient's diagnosis is clinically evident as follows:

   AKI Diagnostic Criteria (not graded):

   - **Increase in Serum Creatinine by ≥0.3 mg/dl** (≥26.5 µmol/l) within 48 hours

   or

   - **Increase in Serum Creatinine to 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days;**

   or

   - Urine volume <0.5 ml/kg/h for 6 hours.

   Acute Kidney Injury Network (AKIN) Severity Staging Criteria

   - **Stage 1: Increase of more than or equal to 0.3 mg/dl** (≥26.5 mmol/l) **or increase to more than or equal to150% to 200% (1.5- to 2-fold) from baseline or** Urine output less than 0.5 ml/kg/h for more than 6 hours
   - Stage 2: Increased to more than 200% to 300% (>2- to 3-fold) from baseline **or** Urine output less than 0.5 ml/kg/h for more than 12 hours
   - Stage 3: Increased to more than 300% (>3-fold) from baseline, **or** more than or equal to 4.0 mg/dl (≥354 mmol/l) with an acute increase of at least 0.5 mg/dl (44

mmol/l) **or** on RRT **or** Urine output less than 0.3 ml/kg/h for 24 hours or anuria for 12 hrs.

9. **The clinical information contained in the medical record is consistent with evidence based guidelines for establishing the diagnosis of AKI. Please note that the reviewer's listed criteria for AKI are "OR" statements and that only <u>one</u> of the criteria is required for the definition of AKI to be met. A fall in urinary output is only one possible criterion, but it is *not* required. In this case, the serum creatinine went from 0.8 to 1.36 to 1.02. This is clearly greater than a 0.3 mg/dl and > 1.5 increase in the creatinine from baseline. AKI was appropriately diagnosed and coded.**

10. **A team of licensed providers, responsible for the care of the patient, entered the diagnoses into the medical record. Coding Clinic** (reference below) **states "<u>diagnosing a patient's condition is *solely* the responsibility of the provider. Only the physician, or other qualified healthcare practitioner *legally accountable for establishing the patient's diagnosis*, can "diagnose" the patient… While physicians may use a particular clinical definition or set of clinical criteria to establish a diagnosis, the code is based on his/her documentation, not on a particular clinical definition or criteria. In other words, regardless of whether a physician uses the new clinical criteria for sepsis, the old criteria, his personal clinical judgment, or something else to decide a patient has sepsis (and document it as such), the code for sepsis is the same—as long as sepsis is documented, regardless of how the diagnosis was arrived at, the code for sepsis can be assigned. Coders should not be disregarding physician documentation and deciding on their own, based on clinical criteria, abnormal test results, etc., whether or not a condition should be coded."</u> We would be *incorrect* to ignore the physicians' diagnosis and documentation.**

11. **Inclusion of sepsis and AKI 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 and AKI**(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.

12. 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.

Coding References

<u>Selection of Principal Diagnosis</u>
<u>ICD-10-CM Official Guidelines for Coding and Reporting</u>
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."

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 close monitoring of laboratory studies and urinary output***
- **or** Therapeutic Treatment; ***MET as evidenced by the administration of intravenous fluids and withholding of Lasix and Lisinopril***
- **or** Diagnostic Procedures; ***MET as evidenced by serial monitoring of kidney function studies***
- **or** Extended Length of Hospital Stay,
- **or** Increased Nursing Care and/or Monitoring. ***MET as evidenced by close monitoring of laboratory studies and urinary output, administration and monitoring of intravenous fluids***

➢ ***Please note that only ONE of the above criteria needs to be met in order to make the diagnosis 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 <u>severe</u> 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.

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.

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).

ICD-10-CM Official Guidelines for Coding and Reporting

The Official Guidelines for Coding and Reporting (developed by the four cooperating parties) are a set of rules that have been developed to accompany and complement the official conventions and instructions provided within the ICD-10-CM itself. The instructions and conventions of the classification take precedence over guidelines. These guidelines are based on the coding and sequencing instructions in the Tabular List and Alphabetic Index of ICD-10-CM, but provide additional instruction**. Adherence to these guidelines when assigning ICD-10-CM diagnosis codes is required under the Health Insurance Portability and Accountability Act (HIPAA).**

AHA Coding Clinic Guidelines 2Q 2000 P. 17-18:
Coding professionals may assign and report codes, without physician consultation, to diagnoses and procedures not stated in the physician's final diagnosis **if the diagnoses** and procedures **are specifically documented in the body of the medical record.**

Conventions for ICD-10-CM
ICD-10-CM Official Guidelines for Coding and Reporting
Effective October 1, 2016 - September 30, 2017
Section I. Conventions, general coding guidelines and chapter specific guidelines
A. Conventions for the ICD-10-CM
19. ***Code assignment and Clinical Criteria***

The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis.

ICD-10-CM Official Guidelines for Coding and Reporting FY 2018
ICD-10-CM Official Guidelines for Coding and Reporting
Effective October 1, 2017 - September 30, 2018

In the context of these guidelines, **the term provider is used throughout the guidelines to mean physician or any qualified health care practitioner who is legally accountable for establishing the patient's diagnosis.** Only this set of guidelines, approved by the Cooperating Parties, is official.

- ***Please note, it is the sole responsibility of the patient's provider to legally establish the patient's diagnosis.***

AHA Coding Handbook
Chapter 5: The Medical Record as a Source Document
Introduction
Contents of the Medical Record

Although the pathologist or radiologist provides a written interpretation of a tissue biopsy or an X-ray image, **this is not equivalent to the attending physician's medical diagnosis, which is based on the patient's complete clinical picture. The attending physician is responsible for, and directly involved in, the care and treatment of the patient.**

This would apply to any person who is not the attending physician or a provider directly involved in the care of the patient.

ICD-10-CM Pertinent Codes and Descriptions:
Injury
Kidney
Acute (nontraumatic) N17.9
Necrosis
Tubular (acute, anoxic, renal, toxic) N17.0
Postprocedural N99.0
Failure
Renal
with tubular necrosis (acute) N17.0
Acute N17.9
with cortical necrosis N17.1
with medullary necrosis N17.2
with tubular necrosis N17.0

Diagnostic and Evidence Based Clinical References

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 Guideline/Practice Guideline Recommendation	• **SSC definitions for systemic inflammatory response syndrome (SIRS) includes the presence of at least <u>two of the following clinical criteria:</u>** 1. Temperature, < 36°C or > 38.3°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). [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 Based Guideline/Practice Guideline Recommendation	• The most important change in the revision of the SSC bundles is that the 3-h and 6-h bundles have been combined into a single "hour-1 bundle" with the explicit intention of beginning 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 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-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 Guideline/Practice Guideline Recommendation	• "Despite…limitations, the SIRS criteria have been practical and widely used for quality improvement initiatives (8/9) and awareness campaigns (10) to educate clinicians and the public 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 sepsis…**Determining 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 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, S…Talan, 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/mm^3 or less than 4,000/mm^3, or greater than 10% immature band forms." [p.3] • **"<u>Severe</u> 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 risk…The 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, M…Angus, D.C. (2016). The Third International**

	Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. As found on: *http://jama.jamanetwork.com/article.aspx?articleID=2492881*
Evidence Based Guideline/Practice Guideline Recommendation	• **Sepsis-3 definitions are inconsistent with the ICD-10-CM Official Guidelines for Coding and Reporting (OCG). Adherence to these guidelines when assigning diagnosis codes is *required* under the Health Insurance Portability and Accountability Act (HIPAA).** (https://acphospitalist.org/archives/2016/03/coding-sepsis-confusing-part-2.htm#.WZCl0AvgWOI.email) **While physicians may use a particular clinical definition or set of clinical criteria to establish a diagnosis, the code is based on his/her documentation, not on a particular clinical definition or criteria. In other words, regardless of whether a physician uses the new clinical criteria for sepsis, the old criteria, his personal clinical judgment, or something else to decide a patient has sepsis (and document it as such), the code for sepsis is the same—as long as sepsis is documented, regardless of how the diagnosis was arrived at, the code for sepsis can be assigned**
Source/Reference	**Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. Kidney inter., Suppl. 2012; 2: 1–138. As found on:** ***http://kdigo.org/home/guidelines/acute-kidney-injury/***
Evidence Based Guideline/Practice Guideline Recommendation	• AKI is one of a number of conditions that affect kidney structure and function. AKI is defined by an abrupt decrease in kidney function that includes, but is not limited to, ARF. It is a broad clinical syndrome encompassing various etiologies, including specific kidney diseases (e.g., acute interstitial nephritis, acute glomerular and vasculitic renal diseases); non-specific conditions (e.g., ischemia, toxic injury); as well as extrarenal pathology (e.g., prerenal azotemia, and acute postrenal obstructive nephropathy) • Unfortunately, a precise biochemical definition of ARF was never proposed and, until recently, there was no consensus on the diagnostic criteria or clinical definition of ARF, resulting in multiple different definitions. A recent survey revealed the use of at least 35 definitions in the literature. This state of confusion has given rise to wide variation in reported incidence and clinical significance of ARF. Depending on the definition used, ARF has been reported to affect from 1% to 25% of ICU patients and has lead to mortality rates from 15–60%. • **AKI: acute kidney injury/impairment**

	○ Importantly, by defining the syndrome of acute changes in renal function more broadly, RIFLE criteria move beyond ARF. The term ‘‘acute kidney injury/impairment’’ has been proposed to encompass the entire spectrum of the syndrome from minor changes in markers of renal function to requirement for renal replacement therapy (RRT). Thus, the concept of AKI, as defined by RIFLE creates a new paradigm. **AKI is not ATN, nor is it renal failure. Instead, it encompasses both and also includes other, less severe conditions. Indeed, as a syndrome, it includes patients without actual damage to the kidney but with functional impairment relative to physiologic demand. Including such patients in the classification of AKI is conceptually attractive because these are precisely the patients that may benefit from early intervention. However, it means that AKI includes both injury and/or impairment rather than focusing exclusively on patients with renal failure**. ○ AKI encompasses both Acute Tubular Necrosis (ATN) and renal failure. As a syndrome, “it includes patients without actual damage to the kidney but with functional impairment relative to physiologic demand…. Sustained AKI leads to profound alterations in fluid, electrolyte, acid-base and hormonal regulation. AKI results in abnormalities in the central nervous, immune and coagulation systems”. • **AKI Diagnostic Criteria (not graded):** ○ **Increase in Serum Creatinine by >0.3 mg/dl** (≥26.5 µmol/l) within 48 hours ○ **or** ○ **Increase in Serum Creatinine to 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days**; ○ **or** ○ Urine volume <0.5 ml/kg/h for 6 hours. • **Acute Kidney Injury Network (AKIN) Severity Staging Criteria** ○ **Stage 1: Increase of more than or equal to 0.3 mg/dl** (≥26.5 mmol/l) **or increase to more than or equal to150% to 200% (1.5- to 2-fold) from baseline or** Urine output less than 0.5 ml/kg/h for more than 6 hours ○ Stage 2**:** Increased to more than 200% to 300% (>2- to 3-fold) from baseline **or** Urine output less than 0.5

	ml/kg/h for more than 12 hours ○ Stage 3: Increased to more than 300% (>3-fold) from baseline, **or** more than or equal to 4.0 mg/dl (≥354 mmol/l) with an acute increase of at least 0.5 mg/dl (44 mmol/l) **or** on RRT **or** Urine output less than 0.3 ml/kg/h for 24 hours or anuria for 12 hrs. • RIFLE Severity Staging Criteria ○ Risk: Increase in serum creatinine x 1.5 or GFR decrease >25% or Urine output less than 0.5 ml/kg/h for more than 6 hours ○ Injury: Serum creatinine x 2 or GFR decreased >50% or Urine output less than 0.5 ml/kg/h for more than 12 hours ○ Failure: Serum creatinine x 3, or serum creatinine >4 mg/dl (>354 mmol/l) with an acute rise >0.5 mg/dl (>44 mmol/l) or GFR decreased >75% or Urine output less than 0.3 ml/kg/h for 24 hours or anuria for 12 hrs. ○ Loss: Persistent acute renal failure=complete loss of kidney function >4 weeks ○ End-stage kidney disease: ESRD >3 month • Note: For conversion of creatinine expressed in SI units to mg/dl, divide by 88.4. For both AKIN stage and RIFLE criteria, only one criterion (creatinine rise or urine output decline) needs to be fulfilled. Class is based on the worst of either GFR or urine output criteria. GFR decrease is calculated from the increase in serum creatinine above baseline. For AKIN, the increase in creatinine must occur in 48 hours. For RIFLE, AKI should be both abrupt (within 1–7 days) and sustained (more than 24 hours). When baseline creatinine is elevated, an abrupt rise of at least 0.5 mg/dl (44 mmol/l) to >4 mg/dl (>354 mmol/l) is sufficient for RIFLE class Failure (modified from Mehta et al.23 and the report of the Acute Dialysis Quality Initiative consortium).
Source/Reference	**Acute kidney injury: an increasing global concern. The Lancet. Vol 382. July 13, 2013 (170-179)**
Evidence Based Guideline/Practice Guideline Recommendation	• **Even small acute changes in kidney function can result in short-term and long-term complications**, including chronic kidney disease, end-stage renal disease, and death. Presence of more than one comorbidity results in high severity of illness scores in all medical settings. (page 170) • Several comorbidities, including diabetes mellitus, cardiovascular disease, chronic liver disease, cancer, and complex surgery have been associated with development of acute kidney injury in community, hospital, and critical care settings. (page 172)

	• The established perception that patients who recover from acute kidney injury return to (or approach) normal baseline kidney function has recently been questioned. Normalization of serum creatinine is however not automatically equivalent to complete recovery of renal function. (page 175)
Source/Reference	**Abdel-Kader K. & Palevsky P. (2009). Acute Kidney Injury in the Elderly. *Clin Geriatr Med*. 25(3): 331-358. As found on: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2748997/pdf/nihms113646.pdf***

Evidence Based Guideline/Practice Guideline Recommendation	• Acute kidney injury (AKI) is any sudden reduction in kidney function [p. 1]
	• Urine output after correction of the obstruction does not always correlate with renal recovery [p. 11]
	• **Even 0.3 increases in serum creatinine can result in adverse outcomes** [p. 1]
	• Risk factors for AKI [pp. 4, 10, 25-26]
	  ○ **Advancing age**
	  ○ **Diabetes mellitus**
	  ○ **Hypertension**
	  ○ **Cardiovascular disease**
	  ○ Peripheral vascular disease
	  ○ Congestive heart failure
	  ○ Benign prostatic hypertrophy
	  ○ Malignancies especially with radiation
	  ○ Urinary obstruction such as infection or stones
	  ○ **Medications**
	  ○ Hypercalcemia
	  ○ Decreased blood volume

Selected Coding Clinics

Source/Reference	**Applying Past Issues of AHA Coding Clinic for ICD-9-CM to ICD-10** ***Coding Clinic*, Fourth Quarter 2015: Page 20** **Coding advice or code assignments contained in this issue effective with discharges November 13, 2015.**
Practice Guideline Recommendation	• **In general, clinical information and information on documentation best practices published in Coding Clinic were not unique to ICD-9-CM, and remain applicable for ICD-10-CM** with some caveats. For example, ***Coding Clinic* may still be useful to understand clinical clues** when applying the guideline regarding not coding separately signs or

	symptoms that are integral to a condition. **<u>Users</u> may continue to use that information, as clues—not clinical criteria**. • **As far as previously published advice on documentation is concerned, documentation issues would generally not be unique to ICD-9-CM, and so long as there is nothing new published in *Coding Clinic for ICD-10-CM and ICD-10-PCS* to replace it, the advice would stand.**
Source/Reference	**Use of *Coding Clinic* as Clinical Criteria for Code Assignment** ***Coding Clinic*, Third Quarter 2008 Page: 16** **Effective with Discharges: September 19, 2008**
Practice Guideline Recommendation	**Question:** • Can background clinical information published in Coding Clinic be used as clinical criteria for code assignment? **Answer:** • **No, background material published in Coding Clinic cannot be used as clinical criteria for code assignment**. As stated in Coding Clinic, Second Quarter 1998, pages 4-5: "**Any clinical information published in Coding Clinic, is provided as background material to aid the coder's understanding of disease processes**. The information is intended to provide the coder with 'clues' to identify possible gaps in documentation where additional physician query may be necessary. It is not intended to replace the need for specific physician documentation to substantiate code assignment."
Source/Reference	**Documentation guidelines** ***Coding Clinic*, Second Quarter 2000 Page: 17 to 18** **Effective with discharges: July 1, 2000**
Practice Guideline Recommendation	• **When the documentation in the medical record is clear and consistent, coders may assign and report codes**. If there is evidence of a diagnosis within the medical record, and the coder is uncertain whether it is a valid diagnosis because the documentation is incomplete, vague, or contradictory, it is the coder's responsibility to query the attending physician to determine if this diagnosis should be included in the final diagnostic statement. **All diagnoses should be supported by physician documentation. Documentation is not limited to the face sheet, discharge summary, progress notes, history and physical, or other report designed to capture diagnostic information.**
Source/Reference	**AHA *Coding Clinic* Guidelines 1st Q 2003 P. 22:**

Practice Guideline Recommendation	**Clarification** • "There are some issues with regard to the question in Coding Clinic, Third Quarter 2002, page 21, on acute renal failure due to dehydration, where the only treatment is IV hydration, and BUN and creatinine return to normal. The answer contains the final sentence, "The fact that renal function was not investigated or worked up does not affect code assignment." This was misleading, in that **the renal function in fact would be followed based on close monitoring of the fluid intake and output, as well as the BUN and creatinine. Fluid monitoring requires nursing resources. Even though the only treatment for the acute renal failure is IV hydration, no procedures are done to image or evaluate the kidneys, and treatment with dialysis is not required, it is still appropriate to assign the code for acute renal failure** as the principal diagnosis. In most instances, when dialysis is not required, rehydration corrects the acute renal failure. This would be consistent whether the acute renal failure was due to dehydration or another condition".
Source/Reference	**AHA *Coding Clinic* for ICD-9-CM, 2010 3Q pg 14**
Practice Guideline Recommendation	• **Acute kidney failure (584.X) is not an acute exacerbation of chronic kidney failure.** Acute kidney failure and chronic kidney failure are two separate and distinct conditions. Acute renal failure has an abrupt onset and is potentially reversible. Chronic kidney failure progresses slowly over time and can lead to permanent kidney failure. The causes, symptoms, treatments, and outcomes of acute and chronic are different. End-stage renal disease (585.6) is when the kidneys permanently fail to work. **If both acute and chronic kidney failure are clearly documented, code both.**
Source/Reference	**Clinical Criteria and Code Assignment** ***Coding Clinic*, Fourth Quarter 2016: Page 147** **Coding advice or code assignments contained in this issue effective with discharges October 1, 2016.**
Practice Guideline Recommendation	**Question:** • Please explain the intent of the new ICD-10-CM guideline regarding code assignment and clinical criteria that reads as follows: "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The

	provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." Some people are interpreting this to mean that clinical documentation improvement (CDI) specialists should no longer question diagnostic statements that don't meet clinical criteria. Is this true? **Answer:** • **Coding must be based on provider documentation. This guideline is *not* a new concept**, although it had not been explicitly included in the official coding guidelines until now. ***Coding Clinic*** **and the official coding guidelines have *always* stated that code assignment should be based on provider documentation.** As has been repeatedly stated in *Coding Clinic* over the years**, <u>diagnosing a patient's condition is solely the responsibility of the provider. Only the physician, or other qualified healthcare practitioner legally accountable for establishing the patient's diagnosis, can "diagnose" the patient.</u>** As also stated in *Coding Clinic* in the past, clinical information published in *Coding Clinic* does not constitute clinical criteria for establishing a diagnosis, substitute for the provider's clinical judgment, or eliminate the need for provider documentation regarding the clinical significance of a patient's medical condition. • The guideline noted addresses coding, not clinical validation. **It is appropriate for facilities to ensure that documentation is complete, accurate, and appropriately reflects the patient's clinical conditions**. Although ultimately related to the accuracy of the coding, clinical validation is a *separate* function from the coding process and clinical skill. The distinction is described in the Centers for Medicare & Medicaid (CMS) definition of clinical validation from the Recovery Audit Contractors Scope of Work document and cited in the AHIMA Practice Brief ("Clinical Validation: The Next Level of CDI") published in the August issue of JAHIMA: "Clinical validation is an additional process that may be performed along with DRG validation. Clinical validation involves a clinical review of the case to see whether or not the patient truly possesses the conditions that were documented in the medical record. Clinical validation is performed by a clinician (RN, CMD, or therapist). Clinical validation is beyond the scope of DRG (coding) validation,

	and the skills of a certified coder. This type of review can only be performed by a clinician or may be performed by a clinician with approved coding credentials." • **While physicians may use a particular clinical definition or set of clinical criteria to establish a diagnosis, the code is based on his/her documentation, not on a particular clinical definition or criteria. In other words, regardless of whether a physician uses the new clinical criteria for sepsis, the old criteria, his personal clinical judgment, or something else to decide a patient has sepsis (and document it as such), the code for sepsis is the same—as long as sepsis is documented, regardless of how the diagnosis was arrived at, the code for sepsis can be assigned**. **Coders should not be disregarding physician documentation and deciding on their own, based on clinical criteria, abnormal test results, etc., whether or not a condition should be coded.** For example, if the physician documents sepsis and the coder assigns the code for sepsis, and a clinical validation reviewer later disagrees with the physician's diagnosis, that is a clinical issue, but it is not a coding error. By the same token, coders shouldn't be coding sepsis in the absence of physician documentation because they believe the patient meets sepsis clinical criteria. A facility or a payer may require that a physician use a particular clinical definition or set of criteria when establishing a diagnosis, but that is a clinical issue outside the coding system.

Conclusion

Memorial Medical Center provided medically necessary services to Jane Doe with the expectation that those services would be reimbursed according to the documentation in all UHDDS communications. Memorial Medical Center respectfully requests that you reconsider this claim and require payment to be made to Memorial Medical Center for the services provided to Jane Doe in this case.

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

Respectfully,

Denise Wilson MS, RN, RRT

Submitted with the authority of the Provider,

Please return all correspondence to:

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Towson, MD, 21286

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