

TEXAS CHILDREN'S HOSPITAL
EVIDENCE-BASED OUTCOMES CENTER
Treatment of Migraine Headaches in the Pediatric Emergency Center
Evidence Summary

Inclusion Criteria

- Chief complaint of migraine headaches
- Age <21 years

Exclusion Criteria

- Age >21 years
- Pregnancy

Background

Headache disorders is one of the most common chief complaints noted in the emergency rooms in the United States. A large portion of these visits are from patients suffering with migraines. ⁽¹⁾ There is variation in practice in the treatment of migraine headaches and whether therapy is given to prevent recurrence. This evidence summary will address questions related to the treatment strategy and provide clinical decision support related to this topic.

Critically Analyze the Evidence

The **GRADE criteria** were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of evidence is rated and how a strong versus a weak recommendation is established.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
WEAK	Desirable effects closely balanced with undesirable effects
Quality	Type of Evidence
High	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
Moderate	Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies
Low	Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

PICO Question 1: For the treatment of migraine headache in pediatric and adolescent patients presenting to the emergency center, is intravenous ketorolac compared to IV metoclopramide, IV sodium valproate, or IV magnesium sulfate more effective for pain?

Recommendation(s):

- Weak recommendation with moderate quality evidence to consider IV Metoclopramide for the treatment of migraine headaches in pediatric and adolescent patients presenting to the ED.
- Weak recommendation with moderate quality evidence to consider IV Ketorolac over IV Sodium Valproate for the treatment of migraine headaches in pediatric and adolescent patients presenting to the ED.
- Weak recommendation with moderate quality evidence to consider IV Magnesium for pediatric and adolescent patients with unsuccessful treatment with first line therapy for migraine headaches.

In a meta-analysis of three randomized controlled trials of IV metoclopramide used for acute migraine attacks in adults, metoclopramide was shown to significantly reduce migraine pain in comparison to the placebo group (OR 2.84, 95% CI 1.05-7.68). Three studies comparing metoclopramide to chlorpromazine and prochlorperazine found that the use of metoclopramide resulted in an increased odds of a higher requirement for rescue medication (OR 2.08; 95% CI: 1.04-4.17). ⁽²⁾ In a more recent trial of prochlorperazine versus metoclopramide for the treatment of migraine, both medications were efficacious for adult ED patients with acute migraine (mean difference in numeric rating scale scores = 0.3; 95% CI: -1.0 to 1.6). ⁽³⁾ A 2015 meta-analysis that compared metoclopramide to placebo or active comparator found that there was not a statistical difference between groups (OR 0.8, 95% CI 0.4 - 1.4). ⁽⁴⁾

There exists a paucity of evidence comparing IV valproic acid (VPA) to commonly used antimigraine therapies. Friedman compared IV VPA to another phenothiazine antiemetic (metoclopramide) and found VPA to be clinically and statistically less effective in reducing pain scores. Patients receiving IV VPA improved by 1.1 fewer points on a 0-10 pain scale than patients receiving IV ketorolac. (95% CI: -2.2 to -0.2). Investigators established that a difference of 1.3 points on the pain scale was necessary to reach a threshold of clinical significance. Likewise, 69% of patients receiving VPA in this study required rescue medication. (5) A single study concluded IV VPA failed to significantly improve pain when compared to IV prochlorperazine, and 79% of patients receiving VPA required rescue medication one hour after treatment. (6) A single study comparing the efficacy of IV VPA with intramuscular metoclopramide combined with subcutaneous sumatriptan reported changes in pain score from “severe” or “moderate” to “mild” or “none” for 53% of patients in the IV VPA group by one hour and 60% of patients by two hours. The mean reduction in pain scores was significantly greater for patients who received IV VPA (mean difference 0.91, p=0.48, 95% CI: 0.009-1.81). (7) A single, non-randomized open label study of IV VPA reported patients experienced a reduction in pain from “severe” or “moderate” to “mild” or “no” pain within 60 minutes for 75% of patients (OR 7.187; 95% CI: 1.32-38.95). (8) Two observational studies reviewed report an approximate 30% reduction in pain scores with the administration of IV VPA for headache treatment. (9,10)

A systematic review of the efficacy of ketorolac (KET) in migraine pain relief in the emergency department was recently conducted in 2013. Three studies (n = 130) compared parenteral KET to meperidine with another agent (either promethazine or hydrazine) using a 10-point scale to assess pain relief 60 minutes after treatment. Overall, the pooled estimates failed to identify a statistically significant difference in pain relief (WMD = 0.44; 95% CI: -0.49-1.38), and heterogeneity was low ($I^2 = 0\%$). A study comparing ketorolac to meperidine found that ketorolac was significantly less effective with only 6% of ketorolac patients achieving complete pain relief at 60 min compared to 30% of patients receiving meperidine. There was no difference in pain relief at 60 minutes between KET and phenothiazine agents (WMD = 0.82; 95% CI: -1.33-2.98). The review concluded that ketorolac was an overall effective agent. (11) In a 2004 randomized controlled trial (RCT), ketorolac was shown to more effectively reduce pain than nasal sumatriptan. (12) Although, another RCT within the same year found that prochlorperazine had a higher percentage of patients successfully treated (difference 30%; 95% CI 8-52%). (13)

A meta-analysis looking at 1,203 abstracts and 5 randomized control trials failed to demonstrate a beneficial effect of IV magnesium in terms of reduction in pain relief in acute migraine in adults. The study showed no statistical difference in terms of the need for rescue medication. Patients that were treated with magnesium were more likely to report side-effects. The meta-analysis demonstrated a non-statistical difference in the percentage of patients with pain relief after 30 minutes (pooled risk difference – 0.07 (95% CI: -0.23-0.09). (14) A 2014 retrospective review of 20 children in the emergency department that received a 30 mg/kg dose of magnesium found that 35% of patients had a favorable response with no major side effects. (15)

PICO Question #2: For the treatment of migraine headache in pediatric and adolescent patients presenting to the emergency center, is dihydroergotamine (DHE) effective to reduce pain?

Recommendation: Weak recommendation with very low quality evidence to consider IV dihydroergotamine for pediatric and adolescent patients with unsuccessful treatment with first line therapy for migraine headaches.

A review of the literature revealed two observational studies that reported effects of treatment with DHE on headache freedom. A 2011 retrospective review of 163 adult patients that were admitted for DHE treatment reported that 67% of the patients with migraines reported headache freedom during treatment. (16) Kabbouche 2008 investigated the effectiveness of DHE in 32 patients with migraines. The study reported that 74.4% of patients were headache free at discharge. (17) The American Headache Society guidelines list intravenous DHE as a medication that is “probably effective” for the treatment of migraines. (18) A weak recommendation with low quality evidence to offer DHE to patients with migraine headaches in the emergency department was made by the Canadian Headache Society. (19)

PICO Question #3: For treatment of migraines or headaches in pediatric and adolescent patients presenting to the EC, does 20 ml/kg compared to 10 ml/kg fluid bolus improve care?

Recommendation: Strong recommendation with low quality evidence that a 20 ml/kg intravenous bolus of normal saline followed by maintenance IV fluids along with abortive treatment should be given to patients presenting to the emergency department with migraines or headaches.

There is a paucity of literature on the topic of the most effective volume for normal saline boluses in patients with migraine headaches presenting to the emergency department. The one trial found randomized patients that had already received 10 ml/kg normal saline boluses to an additional bolus (to equal a total of 20 ml/kg) or no bolus. There was no difference noted in the pain scores between the two groups (p=0.936). (20)

PICO Question #4: For the treatment of migraines or headaches in pediatric and adolescent patients presenting to the EC, does the use of steroids prevent headache recurrence?

Recommendation: Strong recommendation with moderate quality evidence that a one-time dose of IV dexamethasone should be administered to pediatric patients with migraines or headaches prior to discharge from the emergency center.

Remarks: Dexamethasone is contraindicated if given within the last seven days or if the patient has a hypersensitivity to dexamethasone.

Three meta-analyses were found that reported findings on the use of dexamethasone to prevent headache recurrence. Coleman 2008 listed a significant reduction in the recurrence rates of headaches in the patients treated with dexamethasone compared to those that received usual treatment (relative risk [RR] 0.74, 95% CI 0.6-0.9; number needed to treat [NNT] 9, 95% CI 6-25). ⁽²¹⁾ Dexamethasone was found to benefit patients when added to standard treatment for migraines in the emergency department (RR 0.87; 95% CI 0.80-0.95) by providing a pooled absolute risk reduction of 9.7% for moderate to severe headache in 24-to-72 hours. ⁽²²⁾ A 2015 meta-analysis reported that there was a reduction in headache occurrence (56%) and acute migraine attacks (68%) in most patients with the use of corticosteroids. ⁽²³⁾ A 2013 Best Evidence Report on this topic recommended to consider a single dose of intravenous dexamethasone prior to discharge in adults who received treatment for migraines in the emergency center. ⁽²⁴⁾

Critical Points of Evidence

Evidence Supports

- Consider IV metoclopramide for the treatment of migraine headaches in pediatric and adolescent patients presenting to the ED. ⁽²⁻⁴⁾
– Weak recommendation, moderate quality evidence
- Consider IV ketorolac over IV sodium valproate for the treatment of migraine headaches in pediatric and adolescent patients presenting to the ED. ⁽⁶⁻¹³⁾ – Weak recommendation, moderate quality evidence
- Consider IV magnesium for pediatric and adolescent patients with unsuccessful treatment with first line therapy for migraine headaches. ^(14,15) – Weak recommendation, moderate quality evidence
- Consider IV dihydroergotamine for pediatric and adolescent patients with unsuccessful treatment with first line therapy for migraine headaches. ⁽¹⁶⁻¹⁹⁾ – Weak recommendation, very low quality evidence
- Administer a 20 ml/kg intravenous bolus of normal saline followed by maintenance IV fluids along with abortive treatment to patients presenting to the emergency department with migraines or headaches. ⁽²⁰⁾ – Strong recommendation, low quality evidence
- Administer a one-time dose of IV dexamethasone prior to discharge to patients receiving treatment for migraines or headaches in the emergency center. ⁽²¹⁻²⁴⁾ – Strong recommendation, moderate quality evidence

Dihydroergotamine (DHE) Dosing

Age / Weight	Premedicate with	DHE 1 st		DHE Dosing Upon Admission	Once admitted, premedicate with
<9 and/or <30 kg	Zofran 0.15 mg/kg IV	0.1 mg/dose	If severe nausea occurs with dose, decrease to highest tolerated dose and continue	0.2 mg/dose every 6 hours over 1 hour. Increase by 0.1 mg/dose until MAX of 1 mg/dose or patient experiences undesirable side effects (severe nausea/vomiting) then decrease to highest tolerated dose and continue every 6 hours	Metoclopramide 0.2 mg/kg IV (MAX 10 mg)
9-12 years and ≥30 kg	Zofran 0.15 mg/kg IV	0.15 mg/dose	If severe nausea occurs with dose, decrease to highest tolerated dose and continue	0.3 mg/dose every 6 hours over 1 hour Increase by 0.15 mg/dose until MAX of 1 mg/dose or patient experiences undesirable side effects (severe nausea/vomiting) then decrease to highest tolerated dose and continue every 6 hours	Metoclopramide 0.2 mg/kg IV (MAX 10 mg)
>12 years and DHE naïve	Zofran 0.15 mg/kg IV	0.25 mg/dose	If severe nausea occurs with dose, decrease to highest tolerated dose and continue	0.5 mg/dose every 6 hours over 1 hour Increase by 0.25 mg/dose until MAX of 1 mg/dose or patient experiences undesirable side effects (severe nausea/vomiting) then decrease to highest tolerated dose and continue every 6 hours	Metoclopramide 0.2 mg/kg IV (MAX 10 mg)
>12 years and not DHE naïve	Zofran 0.15 mg/kg IV	0.5 mg/dose	If severe nausea occurs with dose, decrease to highest tolerated dose and continue	1 mg/dose every 8 hours over 1 hour If patient develops undesirable side effects then decrease to 0.75 mg/dose every 8 hours.	Metoclopramide 0.2 mg/kg IV (MAX 10 mg)

TCH Evidence-Based Outcomes Center
Migraine Treatment in the Emergency Center Algorithm
 (Developed by the Emergency Medicine Service in partnership with Neurology)

Definitions: ICHD-II Migraine classification:
Migraine without aura: At least 5 attacks fulfilling the following criteria
 At least 2 of the following

- Unilateral location (often bilateral frontal in pediatrics)
- Pulsating quality
- Moderate or severe pain intensity
- Aggravated by or causing avoidance of routine physical activity

During headache, at least one of the following:

- Nausea and/or vomiting
- Photophobia AND phonophobia
- Not attributed to another disorder

Migraine with aura: At least 2 attacks fulfilling the following criteria
 One or more of the following fully reversible aura symptoms:

- Visual, sensory, speech/language, motor, brainstem, or retinal

At least two of the following four characteristics:

- At least one aura symptom spreads gradually over 5 minutes, and/or two or more symptoms occur in succession
- Each individual aura symptom lasts 5-60 minutes
- At least one aura symptom is unilateral
- The aura is accompanied, or followed within 60 minutes, by headache

Status migrainosus: One headache attack fulfilling criteria below:

- Occurring in a patient with migraine without aura and/or migraine with aura
- Typical of previous attacks except for its duration and severity
- Both of the following characteristics: Unremitting for >72 hours and pain and/or associated symptoms are debilitating

Dihydroergotamine (DHE) Protocol

Contraindications to DHE:
 Hypersensitivity to DHE, uncontrolled hypertension, ischemic heart disease, angina pectoris, history of myocardial infarction, silent ischemia, or coronary artery vasospasm; hemiplegic or basilar migraine, peripheral vascular disease; sepsis; severe hepatic or renal dysfunction; avoid use within 24 hours of triptan, other serotonin agonists, or ergot-like agents; avoid during or within 2 weeks of discontinuing MAO inhibitors; concurrent use of peripheral and central vasoconstrictors; ergot alkaloids are contraindicated with potent inhibitors of CYP3A4 (includes protease inhibitors, azole antifungals, and some macrolide antibiotics); pregnancy; breast-feeding.

DHE in the Emergency Center:
 Give first dose per protocol. If there is complete resolution of headache (or reduction in pain to baseline) following first dose then patient should be discharged home. Otherwise, they should be admitted for DHE.

Admission for DHE:

1. DHE per protocol, premedicate with metoclopramide per DHE protocol. DHE to be administered over 30-60 minutes.
2. Consider one more bolus dose of valproic acid IV 15 – 20 mg/kg if responded to initial loading dose.
3. Continue ketorolac IV every 6 hours (MAX 20 doses or 5 days)

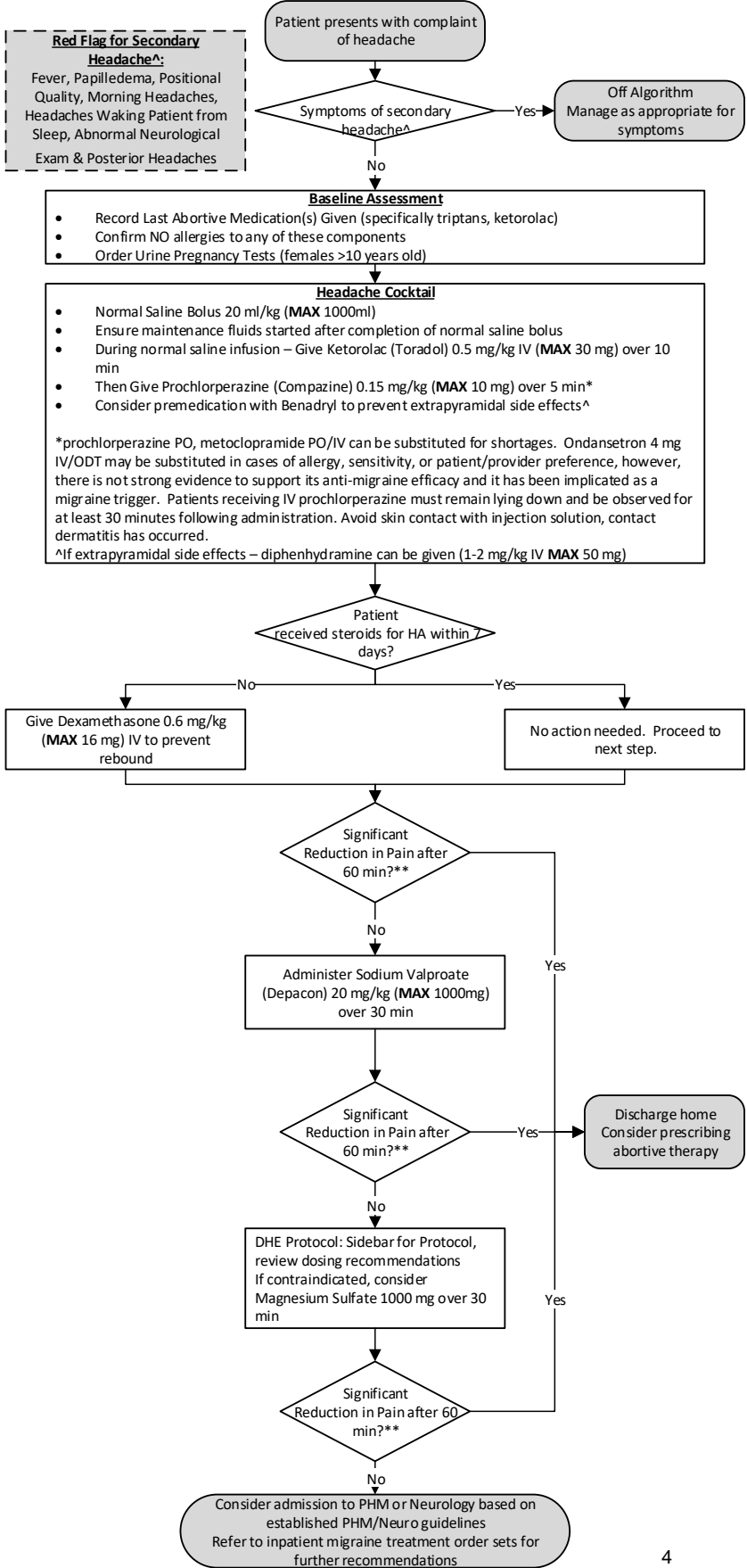
Discontinue DHE:
 Continue DHE until headache reaches baseline pain level then continue for one more dose. Maximum 16 doses. If no improvement after 5 – 6 doses, consult Neurology for further recommendations.

Prior to Discharge

1. If no steroids for headache (HA) within the last 7 days, give dexamethasone 0.6 mg/kg (MAX 16 mg) IV once in the EC prior to discharge to prevent rebound headache.
2. Consider prescribing abortive medication (NSAID) and/or antiemetic if associated with nausea/vomiting
3. Neurology consult to determine if triptan recommended or to consider prescribing preventative medication for patients with frequent attacks or with less frequent attacks with cause significant disability, suboptimal response to acute treatment, and/or those at risk of medication overuse headaches.

Endpoints**

- Steps 1 – 2 work 93% of the time. If not working, reassess and evaluate for mood/anxiety disorder.
- For episodic migraine, should target at least 50% reduction in pain.
- For chronic migraine (with new exacerbation), should target a return to baseline severity.
- Chronic daily headache must be managed chronically with preventative medications, judicious use of acute medications, strict healthy lifestyle habits, and often psychotherapy



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Clinical Standards Preparation

This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children's Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

Treatment of Migraine Headaches in the Pediatric Emergency Center Content Expert Team

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No relevant financial or intellectual conflicts to report.

Development Process

This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. Review Preparation
 - PICO questions established
 - Evidence search confirmed with content experts
2. Review of Existing External Guidelines
 - National Institute for Health and Clinical Excellence, Headaches – Diagnosis and management of headaches in young people and adults; American Headache Society, The Acute Treatment of Migraine in Adults: The American Headache Society Evidence Assessment of Migraine Pharmacotherapies; Canadian Headache Society, Canadian Headache Society Systematic Review and Recommendations on the Treatment of Migraine Pain in Emergency Settings; Best Evidence Topic Reports, Dexamethasone for Reduction of Migraine Recurrence
3. Literature Review of Relevant Evidence
 - Searched: PubMed, CINAHL, Cochrane Library, Google Scholar
4. Critically Analyze the Evidence
 - 7 meta-analyses, 6 randomized controlled trials, and 6 nonrandomized studies
5. Summarize the Evidence
 - Materials used in the development of the clinical standard, literature appraisal, and any order sets are maintained in a Treatment of Migraine Headaches in the Pediatric Emergency Center evidence-based review manual within EBOC.

Evaluating the Quality of the Evidence

Published clinical guidelines were evaluated for this review using the **AGREE II** criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

This clinical standard specifically summarizes the evidence *in support of* or *against* specific interventions and identifies where evidence is *lacking/inconclusive*. The following categories describe how research findings provide support for treatment interventions.

“Evidence Supports” provides evidence to support an intervention

“Evidence Against” provides evidence against an intervention.

“Evidence Lacking/Inconclusive” indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn *from the evidence*.

The **GRADE** criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
WEAK	Desirable effects closely balanced with undesirable effects
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Low	Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

Recommendations

Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies in the management of migraine headaches in children. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

Approval Process

Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children's Hospital. Content Expert Teams are involved with every review and update.

Disclaimer

Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner should use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient's family, to make the ultimate judgment regarding care.

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Version History

Date	Comments
Jul 2018	Originally completed
Mar 2023	Reaffirmed