



## Complete Summary

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### GUIDELINE TITLE

Erythropoietin.

### BIBLIOGRAPHIC SOURCE(S)

Johnson D. Erythropoietin. Nephrology 2006 Apr;11(S1):S34-40.

Johnson D. Erythropoietin. Westmead NSW (Australia): CARI - Caring for Australians with Renal Impairment; 2004 Jul. 9 p. [19 references]

### GUIDELINE STATUS

This is the current release of the guideline.

## \*\* REGULATORY ALERT \*\*

### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse:** This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [July 31, 2008 - Erythropoiesis Stimulating Agents \(ESAs\)](#): Amgen and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of modifications to certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of prescribing information for Erythropoiesis Stimulating Agents (ESAs). The changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should be initiated.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

## SCOPE

### **DISEASE/CONDITION(S)**

- Chronic kidney diseases
- Anemia

### **GUIDELINE CATEGORY**

Management  
Treatment

### **CLINICAL SPECIALTY**

Family Practice  
Internal Medicine  
Nephrology  
Pediatrics

### **INTENDED USERS**

Physicians

### **GUIDELINE OBJECTIVE(S)**

To review the available clinical evidence pertaining to the effect of erythropoietin on renal failure progression

### **TARGET POPULATION**

Adults and children with chronic kidney disease

### **INTERVENTIONS AND PRACTICES CONSIDERED**

Erythropoietin was considered but not recommended.

### **MAJOR OUTCOMES CONSIDERED**

- Hemoglobin level
- Renal failure progression

## METHODOLOGY

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

**Databases searched:** Medline (1999 to November Week 2, 2003). MeSH terms for kidney diseases were combined with MeSH terms and text words for erythropoietin therapy. The results were then combined with the Cochrane highly sensitive search strategy for randomized controlled trials and MeSH terms and text words for identifying meta-analyses and systematic reviews. The Cochrane Renal Group Specialized Register of Randomized Controlled Trials was also searched for relevant trials not indexed by Medline.

**Date of search:** 16 December 2003.

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

### **Levels of Evidence**

**Level I:** Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

**Level II:** Evidence obtained from at least one properly designed RCT

**Level III:** Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

**Level IV:** Evidence obtained from case series, either post-test or pretest/post-test

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Comparison with Guidelines from Other Groups  
Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Recommendations of Others. Recommendations regarding exercise in chronic kidney disease from the following groups were discussed: Kidney Disease Outcomes Quality Initiative, UK Renal Association, Canadian Society of Nephrology, European Best Practice Guidelines, and International Guidelines.

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Definitions for the levels of evidence (I–IV) can be found at the end of the "Major Recommendations" field.

### **Guidelines**

The weight of clinical evidence indicates that erythropoietin exerts neither a beneficial nor deleterious effect on the progression of renal impairment in patients with chronic renal insufficiency. (Level II Evidence, 6 small randomised controlled trials; clinically relevant outcomes; inconsistent effects)

### **Definitions:**

#### **Levels of Evidence**

**Level I:** Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

**Level II:** Evidence obtained from at least one properly designed RCT

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**Level IV:** Evidence obtained from case series, either post-test or pretest/post-test

### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate management of anemia in patients with chronic kidney disease

### **POTENTIAL HARMS**

Not stated

## **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Living with Illness

### **IOM DOMAIN**

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### **BIBLIOGRAPHIC SOURCE(S)**

Johnson D. Erythropoietin. Nephrology 2006 Apr;11(S1):S34-40.

Johnson D. Erythropoietin. Westmead NSW (Australia): CARI - Caring for Australians with Renal Impairment; 2004 Jul. 9 p. [19 references]

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2006 Apr

### **GUIDELINE DEVELOPER(S)**

Caring for Australasians with Renal Impairment - Disease Specific Society

### **SOURCE(S) OF FUNDING**

Industry-sponsored funding administered through Kidney Health Australia

### **GUIDELINE COMMITTEE**

Not stated

### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Author:* David Johnson (Woolloongabba, Queensland)

### **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

All guideline writers are required to fill out a declaration of conflict of interest.

### **GUIDELINE STATUS**

This is the current release of the guideline.

### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [Caring for Australasians with Renal Impairment Web site](#).

Print copies: Available from Caring for Australasians with Renal Impairment, Locked Bag 4001, Centre for Kidney Research, Westmead NSW, Australia 2145

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- The CARI guidelines. A guide for writers. Caring for Australasians with Renal Impairment. 2006 May. 6 p.

Electronic copies: Available from the [Caring for Australasians with Renal Impairment \(CARI\) Web site](#).

## PATIENT RESOURCES

None available

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