TRUVEN HEALTH ANALYTICS

## COMPENDIA TRANSPARENCY TRACKING FORM

**DATE:** August 2015

**PACKET:** 551

**DRUG:** Lenalidomide

**INDICATION:** Myelodysplastic syndrome, transfusion-dependent anemia in patients at low –r intermediate-1 risk without deletion 5q abnormality

| COMPENDIA TRANSPARENCY REQUIREMENTS | |
|---|---|
| 1 | Provide criteria used to evaluate/prioritize the request (therapy) |
| 2 | Disclose evidentiary materials reviewed or considered |
| 3 | Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest |
| 4 | Provide meeting minutes and records of votes for disposition of the request (therapy) |

**EVALUATION/PRIORITIZATION CRITERIA: C, L, R** *to meet requirement 1

| CODE | EVALUATION/PRIORITIZATION CRITERIA |
|---|---|
| **A** | Treatment represents an established standard of care or significant **advance** over current therapies |
| **C** | **Cancer** or cancer-related condition |
| **E** | Quantity and robustness of **evidence** for use support consideration |
| **L** | **Limited** alternative therapies exist for condition of interest |
| **P** | **Pediatric** condition |
| **R** | **Rare** disease |
| **S** | **Serious**, life-threatening condition |

**Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]**

TRUVEN HEALTH ANALYTICS

**EVIDENCE CONSIDERED:**

*to meet requirements 2 and 4

| CITATION | STUDY-SPECIFIC COMMENTS | LITERATURE CODE |
|---|---|---|
| Raza,A., Reeves,J.A., Feldman,E.J., et al: Phase 2 study of lenalidomide in transfusion-dependent, low-risk, and intermediate-1 risk myelodysplastic syndromes with karyotypes other than deletion 5q. Blood Jan 01, 2008; Vol 111, Issue 1; pp. 86-93. | This was an open-label, single-arm, phase II clinical trial. There was low risk of bias associated with selection of subjects and assessment of outcomes. Data was gathered prospectively for objective outcomes. All subjects were included in the analyses. The results should be interpreted with caution since the study lacked a control group. | S |
| Sibon,D., Cannas,G., Baracco,F., et al: Lenalidomide in lower-risk myelodysplastic syndromes with karyotypes other than deletion 5q and refractory to erythropoiesis-stimulating agents. British Journal of Haematology Mar 2012; Vol 156, Issue 5; pp. 619-625. | This was an open-label, single-arm, phase II clinical trial. There was low risk of bias associated with selection of subjects and assessment of outcomes. Data was gathered prospectively for objective outcomes. All subjects were included in the analyses. The results should be interpreted with caution since the study lacked a control group. | S |
| Yang,Y., Gao,S., Fan,H., et al: Analysis of the efficacy of lenalidomide in patients with intermediate-1 risk myelodysplastic syndrome without 5q deletion. Experimental and Therapeutic Medicine 2013; Vol 6, Issue 3; pp. 803-807. | This was an open-label, single-arm clinical trial. There was low risk of bias associated with selection of subjects and assessment of outcomes. Data was gathered prospectively for objective outcomes. All subjects were included in the analyses. The results should be interpreted with caution since the study lacked a control group. | S |
| Fenaux P, et al. Myelodysplastic syndromes: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 2014; Vol 25(Supp 3): iii57-iii69. | | |

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**Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)**

## CONTRIBUTORS:

*to meet requirement 3

| PACKET PREPARATION | DISCLOSURES | EXPERT REVIEW | DISCLOSURES |
|---|---|---|---|
| Felicia Gelsey, MS | None | Edward Balaban, DO | None |
| Stacy LaClaire, PharmD | None | Jeffrey Patton, MD | None |
| Catherine Sabatos, PharmD, BCOP | None | James E. Liebmann, MD | None |
| | | Keith Thompson, MD | None |
| | | Jeffrey A. Bubis, DO | None |

## ASSIGNMENT OF RATINGS:

*to meet requirement 4

| | EFFICACY | STRENGTH OF RECOMMENDATION | COMMENTS | STRENGTH OF EVIDENCE |
|---|---|---|---|---|
| **MICROMEDEX** | --- | --- | | B |
| Edward Balaban, DO | Evidence Favors Efficacy | Class IIa: Recommended, In Most Cases | Clearly has clinical efficacy in this setting. | N/A |
| Jeffrey Patton, MD | Evidence Favors Efficacy | Class IIa: Recommended, In Most Cases | None | N/A |
| James E. Liebmann, MD | Evidence Favors Efficacy | Class IIa: Recommended, In Most Cases | There is substantial experience with lenalidomide as treatment of myelodysplasia (MDS). The papers reviewed with this submission confirm that a significant number of patients with low or intermediate risk MDS - regardless of whether they harbor del 5q - can have improvement in their transfusion requirements with use of lenalidomide. This is accomplished with an acceptable low probability of adverse reactions to the drug. The ESMO guidelines also support the use of the drug in this setting. | N/A |

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|---|---|---|---|---|
| Keith Thompson, MD | Evidence Favors Efficacy | Class IIb: Recommended, In Some Cases | None | N/A |
| Jeffrey A. Bubis, DO | Evidence Favors Efficacy | Class IIb: Recommended, In Some Cases | Although the data is not from randomized trials, it is compelling and it appears effective, particularly in patients who have failed or are not candidates for standard therapy such as hypomethylating agents. | N/A |