**COMPENDIA TRANSPARENCY TRACKING FORM**

**DATE:** September 27, 2023

**OFF-LABEL ID #:** 1413

**DRUG NAME:** Ceritinib

**OFF-LABEL USE:** Non-small cell lung cancer ROS1-rearrangement, locally advanced or metastatic, in patients previously treated with non-targeted standard therapy

| 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, S, 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)]**

## EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

| CITATION | LITERATURE CODE |
|---|---|
| Lim, SM, Kim, HR, Lee JS, et al: Open-label, multicenter, phase II study of ceritinib in patients with non-small-cell Lung cancer harboring ROS1 rearrangement. J Clin Oncol Aug 10, 2017; Vol 35, Issue 23; pp. 2613-2618. Pubmed ID: 28520527 | S |
| Owen DH, Singh N, Ismaila N, Masters G, Riely GJ, Robinson AG, Schneider BJ, Jaiyesimi IA. Therapy for Stage IV Non-Small-Cell Lung Cancer With Driver Alterations: ASCO Living Guideline, Version 2023.2. J Clin Oncol. 2023 Aug 20;41(24):e63-e72. doi: 10.1200/JCO.23.01055. Epub 2023 Jul 11. PMID: 37433095. | S |
| Parisi, F, Rossi, G, Biello, F, et al: Current state of the art on the diagnosis and the role of target therapy for treatment of ROS1-rearranged non-small cell lung cancer: a narrative review. Precis Cancer Med 2022; Vol 5, p. 25. | 4 |

**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 |
|---|---|---|---|
| Stacy LaClaire, PharmD | None | | |
| Catherine Sabatos, PharmD | None | | |
| | | John D Roberts | None |
| | | Jeffrey Klein | None |
| | | Richard LoCicero | Incyte Corporation<br><br>Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months. |

## ASSIGNMENT OF RATINGS:

*to meet requirement 4

| | EFFICACY | STRENGTH OF RECOMMENDATION | COMMENTS | STRENGTH OF EVIDENCE |
|---|---|---|---|---|
| **MERATIVE MICROMEDEX** | Evidence Favors Efficacy | Class IIa: Recommended, in Most Cases | | B |
| Jeffrey Klein | Evidence Favors Efficacy | Class IIb: Recommended, in Some Cases | The use of Ceritinib in previously treated NSCLC ROS-1 rearrangement patients demonstrated a favorable overall response and duration of response. The study was small and the majority of the patients were female. The degree of adverse effects of the grade 1 and 2 level were high. | |
| Richard LoCicero | Evidence Favors Efficacy | Class IIa: Recommended, in Most Cases | A single-arm phase II trial established efficacy of ceritinib in previously treated patients with ROS1 rearranged advanced non-small cell lung cancer. Additionally, American Society of Clinical Oncology guidelines support the use of ceritinib in this population | |

| | | | | |
|---|---|---|---|---|
| Todd Gersten | Effective | Class IIa: Recommended, in Most Cases | In a small Asian study, ceritinib demonstrated robust and durable responses in ROS1-rearranged NSCLC in the second line after previous non-targeted treatment. | |