TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: **APRIL 2015**

PACKET: **1191**

DRUG: **Peginterferon alfa-2b**

INDICATION: **Essential thrombocythemia**

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: **A, 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
Alvarado,Y., Cortes,J., Verstovsek,S., et al: Pilot study of pegylated interferon-alpha 2b in patients with essential thrombocythemia. Cancer Chemother Pharmacol Jan 2003; Vol 51, Issue 1; pp. 81-86.	This was an open-label, single-arm phase II clinical trial. There was low risk of bias associated with selection of cohorts 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
Jabbour,E., Kantarjian,H., Cortes,J., et al: PEG-IFN-(alpha)-2b therapy in BCR-ABL-negative myeloproliferative disorders: Final result of a phase 2 study. Cancer Nov 01, 2007; Vol 110, Issue 9; pp. 2012-2018.	This was an open-label, single-arm phase II clinical trial. There was low risk of bias associated with selection of cohorts 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
Langer,C., Lengfelder,E., Thiele,J., et al: Pegylated interferon for the treatment of high risk essential thrombocythemia: results of a phase II study. Haematologica. Oct 2005; Vol 90, Issue 10; pp. 1333-1338.	This was an open-label, single-arm phase II clinical trial. There was low risk of bias associated with selection of cohorts 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

Samuelsson,J., Hasselbalch,H., Bruserud,O., et al: A phase II trial of pegylated interferon alpha-2b therapy for polycythemia vera and essential thrombocythemia: feasibility, clinical 2Band biologic effects, and impact on quality of life. Cancer Jun 01, 2006; Vol 106, Issue 11; pp. 2397-2405.	This was an open-label, single-arm, phase II feasibility study. There was low risk of bias associated with selection of cohorts 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

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
Margi Schiefelbein, PA	None	Edward Balaban, DO	None
Stacy LaClaire, PharmD	None	James E. Liebmann, MD	None
Felicia Gelsey, MS	None	Jeffrey Patton, MD	None
		Jeffrey A. Bubis, DO	Other payments: Dendreon
		Keith Thompson, MD	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 IIb: Recommended, In Some Cases	Although clinically effective; the majority of the experience suggests higher clinical toxicity – it would then appear that alternate therapies including Interferon alfa-2a might be preferable.	N/A

James E. Liebmann, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Interferon has been recognized as an effective treatment for essential thrombocytosis (ET) for decades. Thus, the results reviewed here showing a high remission rate in patients with ET treated with Pegintron are believable. Pegintron is better tolerated than interferon when directly compared in other disorders, so the relatively low rate of adverse events in these trials is to be expected. The real question is which patients with ET need interferon. Most patients can have good disease control with aspirin, hydroxyurea, or anagrelide. However, for those few patients with ET who cannot tolerate or do not respond to these drugs, Pegintron is a reasonable option.	N/A
Jeffrey Patton, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Reasonable response rates.	N/A
Jeffrey A. Bubis, DO	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	The published data is limited, but compelling. This can be considered in patients that have exhausted conventional treatment options.	N/A
Keith Thompson, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	None	N/A