TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Dasatinib

INDICATION: Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, newly diagnosed

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, 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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Kantarjian, H., et al: Dasatinib versus imatinib in newly diagnosed chronicphase chronic myeloid leukemia. New England Journal of Medicine Jun 17, 2010; Vol 362, Issue 24; pp. 2260-2270.	Study methodology comments: This was a randomized, open-label, multicenter, comparative trial with many strengths. This evaluation included the study protocol which was available online on NEJM. Strengths of the study included 1) defined primary and secondary outcomes; 2) defined clinical response and outcome measures; 3) defined chronic-phase CML; 4) confirmed response for subjects achieving first complete cytogenetic response at month 12; 5) had both inclusion and exclusion criteria; 6) compared baseline characteristics of groups; 7) explained method of randomization; 8) assessed medication compliance; 9) conducted power analysis; 10) efficacy analyses included the intent-totreat population; 11) provided 95% confidence intervals; 12) controlled the effect of potential confounding factors on treatment outcome; 13) defined post hoc analyses; 14) used standard of care as the control; and 15) made statistical adjustments to preserve the type I error rate. Weaknesses included 1) possible selection bias since subjects were not recruited randomly or in a consecutive manner; and 2) open-label study without the use of independent assessors.	S
Cortes,Jorge E., et al: Results of dasatinib therapy in patients with early chronic-phase chronic myeloid leukemia. Journal of Clinical Oncology - Official Journal of the American Society of Clinical Oncology Jan 20, 2010; Vol 28, Issue 3; pp. 398-404.	Study methodology comments: This was a randomized, open-label, time-series trial that included two treatment groups. Subjects were randomized to receive dasatinib 100 mg once daily or 50 mg twice daily. The between-group analyses should be interpreted with much caution since they were not powered and the specific tests conducted were not discussed. Additional weaknesses included 1) did not present the method of randomization; 2) did not examine the effect of potential confounding factors on outcomes; and 3) possible selection bias since patients were not recruited in a random or consecutive manner. Strengths were 1) had both inclusion and exclusion criteria; 2) defined response; 3) defined primary outcome; 4) compared baseline characteristics of groups; and 5) the use of a within-subject design to control for confounding effects of patient characteristics.	S
Cortes, Jorge E., Borthakur, G., O'Brien, S., et al: Efficacy of Dasatinib in patients (pts) with previously untreated Chronic Myelogenous Leukemia (CML) in early chronic phase (CML-CP). Blood Nov 20, 2009; Vol 114, Issue 22; p. 143.		3

Cortes, Jorge E., O'Brien, S., Jones, D., et al: Dasatinib (SPRYCEL (R)) in patients (pts) with previously untreated chronic myelogenous leukemia (CML) in chronic phase (CML-CP). Blood Nov 16, 2006; Vol 108, Issue 11; p. 613a.		3
Quintas-Cardama,A., Kantarjian,H., OBrien,S., et al: Dasatinib is safe and effective in patients with previously untreated chronic myelogenous leukemia in chronic phase. Haematologica-The Hematology Journal Jun 2007; Vol 92, Issue 1; pp. 129-129.		3
Borthakur G, et al. Efficacy of dasatinib in patients (pts) with previously untreated chronic myelogenous leukemia (CML) in early chronic phase (CML-CP). J Clin Oncol 26: 2008 (May 20 suppl; abstr 7013)		3
Kantarjian H., et al. Dasatinib compared to imatinib (IM) in patients (pts) with newly diagnosed chronicphase chronic myelogenous leukemia in chronic phase (CML-CP): Twelvemonth efficacy and safety from the phase III DASISION study. J Clin Oncol 28:18s, 2010 (suppl; abstr LBA6500).		3
Atallah EL., et al. Use of dasatinib in patients (pts) with previously untreated chronic myelogenous leukemia (CML) in chronic phase (CML-CP). Journal of Clinical Oncology, 2007 ASCO Annual Meeting Proceedings Part I. Vol 25, No. 18S (June 20 Supplement), 2007: 7005.		3

Cortes J., et al. Efficacy of Dasatinib in Patients (pts) with Previously Untreated Chronic Myelogenous Leukemia (CML) in Early Chronic Phase (CML-CP) Blood (ASH Annual Meeting Abstracts), Nov 2008; 112: 182.		3
Cortes J., et al. Efficacy of Dasatinib in Patients (pts) with Previously Untreated Chronic Myelogenous Leukemia (CML) in Early Chronic Phase (CML-CP). Blood (ASH Annual Meeting Abstracts), Nov 2009; 114: 338.		3
Cortes J., et al. Efficacy of Dasatinib in Patients (pts) with Previously Untreated Chronic Myelogenous Leukemia (CML) in Early Chronic Phase (CML-CP). Blood (ASH Annual Meeting Abstracts), Nov 2007; 110: 30.		3
Cortes, J., et al. Dasatinib (SPRYCEL®) in Patients (pts) with Previously Untreated Chronic Myelogenous Leukemia (CML) in Chronic Phase (CML-CP). Blood (ASH Annual Meeting Abstracts), Nov 2006; 108: 2161.		3
Le Coutre,P.: New developments in tyrosine kinase inhibitor therapy for newly diagnosed chronic myeloid leukemia. CLINICAL CANCER RESEARCH Mar 15, 2010; Vol 16, Issue 6; pp. 1771-1780		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)

TRUVEN HEALTH ANALYTICS

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Amy Hemstreet, PharmD	None	Jeffrey F. Patton, MD	None
Stacy LaClaire, PharmD	None	Susan Goodin, PharmD	None
Felicia Gelsey, MS	None	Thomas McNeil Beck, MD	None
		John M. Valgus, PharmD	None
		Gerald J. Robbins, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Jeffrey F. Patton, MD	Effective	Class I: Recommended	None	N/A
Susan Goodin, PharmD	Effective	Class I: Recommended	Evidence from a Phase III trial, with the comparator being the standard of care, revealed dasatinib was more effective than the standard of care in cytogenetics and molecular responses. While there is only one randomized Phase III study, it revealed effectiveness and is recommended.	N/A
Thomas McNeil Beck, MD	Effective	Class I: Recommended	None	N/A
John M. Valgus, PharmD	Effective	Class I: Recommended	Data clearly shows dasatinib is effective for this indication. Only weakness is lack of long-term data.	N/A
Gerald J. Robbins, MD	Effective	Class I: Recommended	None	N/A