TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Hydroxyurea

INDICATION: Intracranial meningioma, recurrent after surgery and radiotherapy

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**
*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
Chamberlain MC. Hydroxyurea for recurrent surgery and radiation refractory high-grade meningioma. J Neurooncol 2012;107(2):315-321.	Study methodology comments: This was a retrospective observational study. There was low risk of bias with selection of cohort and assessment of outcome. Data was gathered from medical records. All subjects were included in the analyses. The study lacked a control or active comparator group.	S
Chamberlain MC & Johnston SK. Hydroxyurea for recurrent surgery and radiation refractory meningioma: a retrospective case series. J Neurooncol 2011;104(3):765-771.	Study methodology comments: This was a retrospective observational study. There was low risk of bias with selection of cohort and assessment of outcome. Data was gathered from medical records. All subjects were included in the analyses. The study lacked a control or active comparator group.	S
Hahn,B.M., Schrell,U.M.H., Sauer,R., et al: Prolonged oral hydroxyurea and concurrent 3d-conformal radiation in patients with progressive or recurrent meningioma: Results of a pilot study. Journal of Neuro-Oncology Sep 2005; Vol 74, Issue 2; pp. 157-165		3
Kim,M.-S., Yu,D.-W., Jung,Y.-J., et al: Long-term follow-up result of hydroxyurea chemotherapy for recurrent meningiomas. Journal of Korean Neurosurgical Society 2012; Vol 52, Issue 6; pp. 517-522.		3
Loven,D., Hardoff,R., Sever,Z.B., et al: Non-resectable slow-growing meningiomas treated by hydroxyurea. Journal of Neuro-Oncology Mar 2004; Vol 67, Issue 1-2; pp. 221-226.		3

Mason,W.P., Gentili,F., MacDonald,D.R., et al: Stabilization of disease progression by hydroxyurea in patients with recurrent or unresectable meningioma. Journal of Neurosurgery 2002; Vol 97, Issue 2; pp. 341-346.		3
Newton,H.B., Slivka,M.A., and Stevens,C.: Hydroxyurea chemotherapy for unresectable or residual meningioma. Journal of Neuro-Oncology 2000; Vol 49, Issue 2; pp. 165-170.		3
Reardon,D.A., Norden,A.D., Desjardins,A., et al: Phase II study of Gleevec((registered trademark)) plus hydroxyurea (HU) in adults with progressive or recurrent meningioma. Journal of Neuro-Oncology Jan 2012; Vol 106, Issue 2; pp. 409-415.		3
Rosenthal,M.A., Ashley,D.L., and Cher,L.: Treatment of high risk or recurrent meningiomas with hydroxyurea. Journal of Clinical Neuroscience 2002; Vol 9, Issue 2; pp. 156-158.		3
Schrell,U.M.H., Rittig,M.G., Anders,M., et al: Hydroxyurea for treatment of unresectable and recurrent meningiomas. II. Decrease in the size of meningiomas in patients treated with hydroxyurea. Journal of Neurosurgery May 1997; Vol 86, Issue 5; pp. 840-844.		3

Mazza,E., Reni,M., Lombardi,G., et al: A randomized phase II trial of hydroxyurea (plus or minus) imatinib in the treatment of recurrent or progressive meningiomas. European Journal of Cancer Sep 2013; Vol 49 SUPPL. 2, p. S791.		3
Swinnen,L.J., Rankin,C., Rushing,E.J., et al: Objective response rate of unresectable benign meningioma to hydroxyurea: Southwest oncology group phase II trial S9811. Neuro-Oncology Nov 2010; Vol 12 SUPPL. 4, pp. iv70-iv71.		3
Moazzam,A.A., Wagle,N., and Zada,G.: Recent developments in chemotherapy for meningiomas: a review. Neurosurg Focus Dec 2013; Vol 35, Issue 6; p. E18.		4
Cusimano,M.D. and Schrell,U.H.M.: Hydroxyurea for treatment of meningioma [5]. Journal of Neurosurgery 1998; Vol 88, Issue 5; pp. 938-939.		4
Paus,S., Klockgether,T., Schlegel,U., et al: Meningioma of the optic nerve sheath: Treatment with hydroxyurea [2]. Journal of Neurology, Neurosurgery and Psychiatry Sep 01, 2003; Vol 74, Issue 9; pp. 1348-1350.		4
Schrell,U.M.H., Rittig,M.G., Koch,U., et al: Hydroxyurea for treatment of unresectable meningiomas [4]. Lancet 1996; Vol 348, Issue 9031; pp. 888-889		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)

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CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	Thomas A. Marsland, MD	None
Felicia Gelsey, MS	None	James E. Liebmann, MD	None
		Jeffrey A. Bubis, DO	Other payments: Dendreon
		John M. Valgus, PharmD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX				B
Edward P. Balaban, DO	Ineffective	Class III: Not Recommended	Data just isn't there to consider hydroxyurea therapy for meningioma any other way.	N/A
Thomas A. Marsland, MD	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	Tumor with no "standard" so treatment might be reasonable for some patients, but evidence is really "soft" to support its use. Only two small retrospective studies of questionable value.	N/A
James E. Liebmann, MD	Ineffective	Class III: Not Recommended	The two studies referenced in this packet, which appear identical in design if not in patient population, show no benefit from hydroxyurea. No tumor responses were reported in either paper and 60% of patients in each study progressed at the first evaluation. The fact that there are no other good drug options for this disease does not justify the use of an ineffective drug.	N/A

Jeffrey A. Bubis, DO	Ineffective	Class III: Not Recommended	There is a paucity of positive outcomes data.	N/A
John M. Valgus, PharmD	Ineffective	Class III: Not Recommended	No radiographic responses, generally well tolerated, evidence does not support use	N/A