SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for otitis media with effusion treatments.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on treatments for otitis media with effusion, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1013#5070.*

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

The Key Questions (KQs)

KQ 1: What is the comparative effectiveness of the following treatment options (active treatments and watchful waiting) in affecting clinical outcomes or health care utilization in patients with OME? Clinical outcomes include changes in: OME signs (middle ear fluid) and symptoms (fullness in ear, difficulty in hearing), objective hearing thresholds, episodes of Acute Otitis Media (AOM), and vestibular function such as balance and coordination. Treatment options include:

a. Tympanostomy tubes
b. Adenoidectomy with or without myringotomy
c. Myringotomy
d. Oral or topical nasal steroids
e. Autoinflation
f. Complementary and alternative medical procedures
g. Watchful waiting
h. Variations in surgical technique or procedure

KQ 2: What is the comparative effectiveness of the different treatment options listed in KQ 1 (active treatments and watchful waiting) in improving functional and health-related quality-of-life outcomes in patients with OME? Outcomes include: Hearing, speech and language development, auditory processing, academic achievement, attention and behavioral outcomes, health-related quality of life, and patient and parent satisfaction with care.

KQ 3: What are the differences in harms or tolerability among the different treatment options?

KQ 4: What are the comparative benefits and harms of treatment options in subgroups of patients with OME? Subgroups include:

a. Patients of different age groups
b. Patients of different racial/ethnic backgrounds
c. Patients in different socioeconomic status groups
d. Patients with comorbidities such as craniofacial abnormalities (e.g., cleft palate), Down syndrome, and existing speech, language, and hearing problems
e. Patients with a medical history of AOM or OME (with and without clinical hearing loss)

KQ 5: Is the comparative effectiveness of treatment options affected by the following: Health insurance coverage, physician specialty, type of facility of the treatment provider, geographic location, continuity of care, or prior inoculation with the pneumococcal vaccine?

Dated: April 12, 2012.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2012–9818 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Local Therapies for the Treatment of Stage I Non-Small Cell Lung Cancer and Endobronchial Obstruction Due to Advanced Lung Tumors

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of Conventional Two-Dimensional External Beam Radiotherapy (2D–EBRT), 3-dimensional conformal radiation therapy (3D–CRT), Intensity-modulated radiation therapy (IMRT), Stereotactic body radiation therapy (SBRT), Proton beam radiotherapy (PBR), Brachytherapy, Radiofrequency ablation, Endobronchial debridement and stents, and Nd-YAG Laser Therapy medical devices. Scientific information is being solicited to inform our Comparative Effectiveness Review of Local Therapies for the Treatment of Stage I Non-Small Cell Lung Cancer and Endobronchial Obstruction Due to Advanced Lung Tumors, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this

comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173.

DATES: Submission Deadline on or before May 25, 2012.

ADDRESSES:

Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–494–0147 or Email: *ehcsrc@ohsu.edu*.

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for local therapies for the treatment of stage I non-small cell lung cancer and endobronchial obstruction due to advanced lung tumors.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on local therapies for the treatment of stage I non-small cell lung cancer and endobronchial obstruction due to advanced lung tumors, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guidesreviews-and-reports/?pageaction=displayproduct&productid=965*.

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/*.

The Key Questions

Question 1

What are the comparative benefits and harms of local nonsurgical therapies for documented (clinical or biopsy) stage I (T1NOMO, T2NOMO) Non-Small Cell Lung Cancer (NSCLC) in adult patients (age 18 years or older) who are not surgical candidates because of the presence of contraindications to major surgery, for example, cardiac insufficiency, poor pulmonary function, presence of severe intercurrent illness, or poor performance status?

Question 2

What are the comparative benefits and harms of local nonsurgical therapies for documented (clinical or biopsy) stage I (T1NOMO, T2NOMO) NSCLC in adult patients (age 18 years or older) whose tumor is deemed operable but decline surgery?

Question 3

1. What are the comparative short- and long-term benefits and harms of local therapies given with palliative or curative intent to patients With stage IIIa NSCLC with endoluminal obstruction of the trachea, main stem, or lobar bronchi and recurrent or persistent thoracic symptoms such as hemoptysis, cough, dyspnea, and post-obstructive pneumonitis?

2. What are the comparative short- and long-term benefits and harms of local palliative therapies in patients with advanced stage (IIIb or IV) NSCLC with endoluminal obstruction of the trachea, main stem, or lobar bronchi and recurrent or persistent thoracic symptoms such as hemoptysis, cough, dyspnea, and post-obstructive pneumonitis?

Dated: April 12, 2012.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2012–9817 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Chronic Venous Ulcers Treatments

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of chronic venous ulcer treatment medical devices. Scientific information is being solicited to inform our Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities report, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished