Coverage Guidance Process efficiencies

Question: Coverage Guidance Process efficiencies

Question source: HERC Staff

Issue: The 2016 coverage guidance monitoring is straining staff resources, with 21 coverage guidances approved in 2014 needing to be scoped and to have an updated evidence search performed. Currently, coverage guidances are considered either "approved" or "retired," and all "approved" coverage guidances are rescanned every two years.

Recommendations:

Option 1: Add a new status for a coverage guidance, "Passive Monitoring," for which additional evidence searches are unlikely to change coverage policy. Such coverage guidances may be cases where evidence is already strong, or the prior recommendation to cover a service would require evidence of ineffectiveness or harm. For these topics, staff would not update the scope statement or perform a new evidence search every two years. Rather these topics would be rescoped and have a new evidence search only if stakeholders request a review or if staff becomes aware of a significant new piece of evidence which might substantially change the Coverage Guidance.

If so, the scope statement would be posted for a 7-day public comment period and brought to EbGS or HTAS. Then, an updated evidence search would be performed and staff would bring a recommendation to EbGS or HTAS about whether to update the coverage guidance as is done during the normal monitoring process. Then if a rescan is in order, the topic would be prioritized with other topics during the annual coverage guidance topic prioritization process. If a coverage guidance is in need of an update but is not prioritized for development, it may be retired.

The new status of a Coverage Guidance would therefore be either:

1) Active monitoring – 2 year standing rereview. Earlier review is possible if there is a dramatic change in the literature.
2) Passive monitoring – do not rescan the literature on a regular basis unless a specific concern is raised
3) Retired

Option 2:

Once a year, in alignment with the annual topic nomination process, staff will solicit requests to revisit all existing coverage guidance topics. Staff will evaluate requests to determine whether newly available evidence or information would suggest a revision of the existing Coverage Guidance or a new Coverage Guidance on the topic. Members of the public may also submit such a request at other times of the year and staff may request such a review based on evidence or information they become aware of through other means.

When a request is submitted, staff will evaluate the new information and make a recommendation as to whether a revision to, or replacement of, the existing coverage guidance may be warranted based on its impact on cost, health outcomes or values and preferences. The

request, as well as a staff recommendation, and any other evidence considered during staff's evaluation of the recommendation, will be provided to the originating subcommittee and considered by the Commission during a regular meeting.

Skin Substitutes for Chronic Skin Ulcers

Coverage Guidance versus Guideline Note alone

Question: Should the coverage guidance on skin substitutes for chronic skin ulcers be dropped, while still applying a guideline note to the Prioritized List?

Question Source: HERC Staff

Issue:

Coverage Guidance history: The Evidence-based Guidelines Subcommittee (EbGS) had passed a draft Coverage Guidance on Skin Substitutes for Chronic Skin Ulcers. This was first brought to VbBS and HERC in March 2016, after which the coverage guidance was revised and sent out for a second public comment period. The public comments were reviewed by EbGS and referred to HERC at the August, 2016 meeting, but were not discussed due to time constraints.

In the interim, staff became aware of a new highly relevant Cochrane systematic review.

Santema, 2016

1. Systematic review and meta-analysis of skin substitutes for diabetic foot ulcers
2. 17 studies (13 studies of skin substitutes compared with standard care, 4 studies of skin substitutes compared to another skin substitute); N=1,655 patients across the trials
3. Results:
    a. Incidence of complete wound closure: RR 1.55 (95% CI 1.30 to 1.85); ARD 15%, NNT 7; k=13; low quality GRADE rating
        a. In the sensitivity analysis, exclusion of studies with higher risk of bias did not significantly alter the estimate of effect RR 1.41 (95% CI 1.21 to 1.89)
    b. Incidence of lower extremity amputation: RR 0.43 (95% CI 0.23 to 0.81); ARD 6%, NNT 16;k=2; very low quality GRADE rating
    c. No difference in ulcer recurrence (k=4) or incidence of infection (k=9) in the meta-analysis
4. Study limitations: lack of blinding, limited f/u, industry funding, high likelihood of publication bias
5. Author conclusions: "Overall, the therapeutic effect of skin grafts and tissue replacements, in conjunction with standard care, shows an increase in the healing rate of foot ulcers and slightly fewer amputations in people with diabetes compared with standard care alone. However, the data available to us was insufficient for us to draw conclusions on the effectiveness of different types of skin grafts or tissue replacement therapies, and evidence of long-term effectiveness is lacking. Furthermore, the potential benefits of skin grafts and tissue replacements should be weighed against the high costs of these products. Finally, it is important to note that skin grafts and tissue replacements cannot be seen as a treatment on their own, but should always be part of the multidisciplinary approach to this complex, chronic disease."

From Adam Obley, MD, MPH from the Center for Evidence-based Policy:

> Because of developments in this topic area over the last year, including the submission of additional studies and the publication of the Cochrane review, it has become increasingly clear that there are serious limitations in the individual study designs and a paucity of direct comparative data. With this in mind, Center staff agree that it is very difficult to draw clinically meaningful distinctions between the various products based on the evidence in the literature.

Ongoing public comment continues to address that cost differentials and logistical issues are key considerations in which product is preferred, which is not at all well captured by the evidence nor available information on costs.

Also, historically, the Prioritized List also does not get into brand preferences (e.g. one type of drug-eluting stent versus another, one brand of DME versus another).

<u>HERC Staff Summary</u>

The Coverage Guidance process for skin substitutes for skin ulcers has been going on for almost a year. Much of the evidence is suboptimal quality and subject to publication bias. Despite this, there appears to be a class effect of skin substitutes (for diabetic foot ulcers at least) based on a recent systematic review, and there is inadequate evidence to really differentiate between brands that have randomized controlled trials. Other factors such as cost and number of applications and ease of use may play a role in preference of one skin substitute over another.

There are elements of the draft coverage guidance, such as wound care requirements, that are still potentially useful to plans.

<u>HERC Staff Recommendations</u>

1. Drop the Coverage Guidance on Skin Substitutes for Chronic Skin Ulcers
2. Request VbBS to evaluate the draft language around criteria for use of a skin substitute and potentially adopt this as part of a Prioritized List Guideline Note. Eliminate reference in this draft guideline note to specific brands of skin substitutes or simply list those that have RCTs.