Cost-Effectiveness of a Polymer-Coated, Paclitaxel-Eluting Stent (Eluvia) Compared to a Polymer-Free, Paclitaxel-Coated Stent (Zilver PTX) for Endovascular Femoropopliteal Intervention in Diabetes Patients: A United States Payer Perspective

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Disclosure

Speaker name:
.....Stefan Müller-Hülsbeck..........................................................

I have the following potential conflicts of interest to report:

☒ Consulting: Terumo, Boston Scientific, Eurocor Tech, Alvimedica
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Study Objective

- Cost-effectiveness analyses are increasingly used to support health technology assessment, and inform decision makers on how best to allocate resources.
- Compare the cost-effectiveness of treatment with the Eluvia drug-eluting stent to Zilver PTX in diabetes patients.
  - Simulation model incorporating clinical outcomes data from the IMPERIAL randomized controlled trial.
  - *Real-world treatment* costs from United States Medicare administrative and claims data of a subset of the Medicare population diagnosed with diabetes.
Overview of Study Design

<table>
<thead>
<tr>
<th>Study Design</th>
<th>State transition model to simulate outcomes and costs of Eluvia compared to Zilver PTX for endovascular femoropopliteal intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perspective</td>
<td>United States Medicare (public insurer for those age 65+ or disabled)</td>
</tr>
<tr>
<td>Clinical Inputs</td>
<td>Obtained from the IMPERIAL randomized trial</td>
</tr>
<tr>
<td>Cost Inputs</td>
<td>Obtained from Medicare administrative and claims data and from published literature; subset of Medicare patients diagnosed with diabetes</td>
</tr>
<tr>
<td>Time Horizon</td>
<td>Patients were followed for one year or until death, whichever came first</td>
</tr>
<tr>
<td>Base Case Analysis</td>
<td><strong>Base case probabilistic sensitivity analysis</strong> (PSA), which entailed (A) sampling a complete set of baseline clinical and cost inputs and (B) running cohorts of 1,000 patients through each arm of the model to obtain the average cumulative cost per patient and predicted probability of retaining primary patency at 1 year</td>
</tr>
<tr>
<td>Sensitivity Analyses</td>
<td>PSAs were performed in which clinical input parameters were changed to values of the secondary clinical outcomes reported in the IMPERIAL trial</td>
</tr>
</tbody>
</table>
Model Structure

- Simulated cohorts of 1,000 patients each enter the model one at a time and are assigned to either ELUVIA or Zilver PTX.
- Each patient is followed monthly, for one year or until death, for clinical events observed in IMPERIAL.
Event probabilities were obtained from IMPERIAL.

Model assigns each patient a probability of each event based on the intervention type and the number of months since the intervention.
# Model Input Parameters

<table>
<thead>
<tr>
<th>Clinical Events</th>
<th>Eluvia</th>
<th>Zilver PTX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of Primary Patency</td>
<td>15.4%</td>
<td>20.7%</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
<td>3.7%</td>
<td>13.6%</td>
</tr>
<tr>
<td>Major Amputation Target Limb</td>
<td>0.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Death</td>
<td>2.1%</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Costs</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Endovascular Intervention</td>
<td>$15,015</td>
<td>$15,015</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
<td>$17,879</td>
<td>$17,879</td>
</tr>
<tr>
<td>Major Amputation Target Limb</td>
<td>$38,989</td>
<td>$38,989</td>
</tr>
</tbody>
</table>

3. United States Medicare inpatient and outpatient administrative and claims data from 2017: total of 41,090 outpatient cases and 32,721 inpatient cases.
**Base Case Analysis**

**Point Estimates from Base Case Probabilistic Sensitivity Analysis**

<table>
<thead>
<tr>
<th></th>
<th>Eluvia</th>
<th>Zilver PTX</th>
<th>(Eluvia – Zilver PTX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected primary patency at 12 months</td>
<td>84.8%</td>
<td>79.7%</td>
<td>Δ+5.1%</td>
</tr>
<tr>
<td>Average cost per patient at 12 months</td>
<td>$15,890</td>
<td>$17,210</td>
<td>Δ-1,320$</td>
</tr>
</tbody>
</table>
Eluvia was dominant (less costly and more effective) in 62.4% of simulations.
Eluvia was cost-effective in 75.7% of all simulations at a threshold of $10,000 per primary patency loss prevented.
Discussion

Summary of Findings:
• Eluvia was dominant to Zilver PTX in 62.4% of PSA simulation trials
• Average cost difference of Eluvia vs. Zilver PTX was $\Delta-1,320$
• An additional 5.1% of Eluvia patients expected to retain primary vessel patency at one year

Strengths:
• Clinical inputs obtained from a randomized controlled trial
• Cost inputs obtained from 2017 Medicare administrative and claims data involving a subset of patients diagnosed with diabetes: 41,090 outpatient cases and 32,721 inpatient cases

Limitations:
• Model did not include other endovascular femoropopliteal interventions
• Most patients enrolled in the IMPERIAL trial had intermittent claudication at the time of initial endovascular intervention [few CLI]
• Patients were only followed for one year after intervention
Conclusion

At one year, the Eluvia drug-eluting stent was more effective and less costly than Zilver PTX, making Eluvia the dominant treatment strategy.
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