**Stakeholders Disagree on When, Not How, to Implement Step Therapy**

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### RESULTS

**1. Disagreement across stakeholders on when to use ST**

**Clinical Criteria, Foundation for Protocol Development**

- **Step therapy (ST)**, a utilization management tool, is meant to motivate safe, clinically appropriate and cost-effective use of drugs
- Research demonstrates ST is common but varies in frequency of use and magnitude

**Implementation of Step Therapy Protocols & Processes**

- In 2019, the Centers for Medicare & Medicaid Services finalized a rule allowing Medicare Advantage plans to use ST for Part B drugs.
- The impact of ST on costs and outcomes is uncertain, however, advocacy organizations have outlined guidance for its use and several states have enacted legislation to ensure patient protections.

**Transparency & Communications**

- To assess multistakeholder consensus on a set of criteria regarding the development, implementation and evaluation of step therapy policies.

### METHODS

1. Convened multistakeholder roundtable (n=16; Patients, physicians, plans, pharmacists, policy & ethics)
2. Used Modified Delphi panel to assess consensus included two rounds of voting and a roundtable discussion
3. Differentiated between standards & best practices (Standard = >75% votes for a standard; Best Practice = >75% votes for standards + best practice)

### RESULTS (cont.)

**2. Agreement on how to develop, communicate, implement and evaluate ST**

- Create a clear and accessible electronic process for contacting the benefits administrator
- Allow opportunity for patient or health care provider to make a request for an exception or appeal
- Establish clinical practice guidelines or compendia are incorporated into the review of clinical evidence
- Benefits administrator weighs administrative costs (i.e., staff time & resources) of reviewing step edits vs. costs to health
- Benefits administrator provides a clear, readily accessible, electronic process for health care provider and patient to submit
- Once benefits administrator grants authorization, approval stands

**3. Majority of criteria (14/21) were standards, while the remaining (7/21) were best practices**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Physical</td>
<td>100%</td>
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<tr>
<td>Chemical</td>
<td>100%</td>
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<tr>
<td>Safety</td>
<td>100%</td>
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<tr>
<td>Pharmacology</td>
<td>100%</td>
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<tr>
<td>Clinical</td>
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### CONCLUSIONS

- It is important to define a set of standards which all stakeholders can agree when step therapy is used.
- These elements can serve as the foundation for criteria measurement, reporting mechanisms and regulatory guidelines.