The Clinical Product Evaluation process is a data-driven, evidence-based mechanism for the Presbyterian Delivery System to navigate the growing medical technology market, intentionally mature and modernize care pathways, and target investment in new medical technologies that significantly benefit both patient outcomes and long-term cost of care.

**The Essentials**

- Clinical products can include both medical devices and pharmacology; these products may or may not require the establishment of new procedures or clinical processes. At Presbyterian, a separate enterprise-wide Pharmacy and Therapeutics (P&T) committee assesses pharmacology products.

- The clinical product evaluation process applies to all areas of the Presbyterian Delivery System and all clinical products with an annual expected financial impact of over $50,000 (as determined by the associated Value Analysis Team (VAT)).

- Clinical trial product evaluations do not follow this process; they are instead managed by the Clinical Research Subcommittee and Institutional Review Board (IRB).

**Program Success**

Successful evaluation of clinical products ensures our patients receive the highest quality, highest value care and that our company’s and patients’ investment in them will facilitate the clinical outcomes we seek.

**How Clinical Product Evaluation Works**

The Clinical Product Evaluation process integrates with Presbyterian’s Value Analysis model, leveraging two existing committees — the Value Assessment Teams (VATs) coordinates proposals and the Value Analysis Steering Committee (VASC) provides oversight. A VASC subcommittee, the New Product Committee (NPC), performs the product evaluations.

**Requesting Clinical Products**

Service Line Clinical Committees or department leaders (where no Service Line Committee exists) submit product proposals to their Value Analysis Team. If the requested new product also requires the creation of a new clinical procedure, the Value Analysis Team (VAT) will engage the Emerging Technology Committee and Medical Executive Committee (MEC) to address privilege requirements.

The New Product Committee reviews the product and its evidence with the Physician Champion and makes an approval designation. If the product is...
approved, the Physician Champion plans and executes the agreed upon product roll out and reports outcomes, as requested, to the New Product Committee. For details about this process, see diagram on page 5.

Clinical products are evaluated for:

- Impact on patient clinical outcomes
- Impact on cost of care
- Breadth of system impact
- Product quality and effectiveness
- Price, storage requirements, regular availability, and packaging
- Contract compliance
- Operation and repair requirements
- Benchmark data
- Necessary education and training
- Safety and OSHA considerations
- Infection Control and engineering considerations
- Waste stream/ environmental impact

The Health Plan’s New Technology Committee and the Delivery System’s Value Analysis Team (VAT) coordinate their reviews as needed, through the Value Based Services Organization (VBSO) and Value Analysis Steering Committee (VASC). While payors are not usually affected by most new clinical products, Health Plan representation on the New Product Committee helps to ensure that potential reimbursement impact, when it does occur, is addressed early.

Service Line leadership can escalate Urgent or Emergency one-time requests to the VAT Sourcing Specialist and Finance. After they have completed a preliminary cost/reimbursement assessment, a final decision on the clinical product will be made by the appropriate Medical Director, Administrator, and/or manager (if applicable).

---

**SERVICES**

Review of Clinical Evidence
- Published clinical trial data (including failed trials), FDA approved documents and letters, GPO partner references, benchmark data, suggested efficiency or safety improvements, patient selection protocols

Financial Review
- Coding, reimbursement, ROI, margin analysis based on 12 months info with payor mix, projected impact to other departments, etc.

**TECHNOLOGY**

Lawson: product contract data
Quality Advisor: outcome data analysis
Epic: treatment, outcome, and revenue data; charge master management

**PEOPLE**

Process Owner: Pete Vlaovic, ICS Executive Director
Dr. Jason Mitchell, CMO
Dr. David Arredondo and Dr. Jayne McCormick
Donna Garcia, VP Finance
Owens and Minor Supply Chain, Purchasing, and Contracting teams
Manager of System Services Analytics

“The Clinical Product Evaluation process helps Presbyterian maintain utilization of high quality, safe, effective and innovative products in a fiscally responsible manner.” — Carlos Ochoa, Cardiovascular Lab Director
Outcome Monitoring and Analysis
- Cost metrics, quality metrics, updated clinical evidence

The New Product Committee is a cross-functional team with representatives from each key stakeholder group. The Owens and Minor Sourcing Specialist for each VAT acts as the value analysis coordinator, tracking proposal progress through the process and coordinating discussions with the vendor and/or Physician Champion.

New Product Committee Membership

<table>
<thead>
<tr>
<th>SERVICES</th>
<th>TECHNOLOGY</th>
<th>PEOPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome Monitoring and Analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Cost metrics, quality metrics,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>updated clinical evidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional ad hoc members include subject matter experts (SMEs) from the Presbyterian Health Plan, Presbyterian Medical Group, and Presbyterian Delivery System.


Measurement of Success

The New Product Committee will establish metric monitoring requirements for each product, based on organizational risk and metric type; the clinical product evaluation process is measured through retrospective review of the estimated clinical and economic outcomes.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measure</th>
<th>Aligns with Aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved Clinical Outcomes</td>
<td>• Representative measures defined for each technology, based on clinical outcome claims</td>
<td>Better Health</td>
</tr>
<tr>
<td></td>
<td>• Appropriate use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Infection rates</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Complications</td>
<td></td>
</tr>
<tr>
<td>Improved Financial Outcomes</td>
<td>• Cost per Case</td>
<td>Cost Leadership</td>
</tr>
<tr>
<td></td>
<td>• Profitability - Margin Analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Length of Stay (LOS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Case times</td>
<td></td>
</tr>
<tr>
<td>Evaluation Accuracy</td>
<td>• Savings: actual vs. projected</td>
<td>Cost Leadership, Better</td>
</tr>
<tr>
<td></td>
<td>• Volume: actual vs. projected</td>
<td>Health</td>
</tr>
<tr>
<td></td>
<td>• Clinical Outcomes: actual vs. projected</td>
<td></td>
</tr>
</tbody>
</table>

The Systems Services Analytics Manager will escalate underperforming metrics to the New Product Committee for further assessment and follow up as needed. The Systems Services Analytics manager will also generate a full portfolio report for presentation to the VASC at least twice a year.

Work in Process/ Future Work

VAT teams are currently implementing the clinical product evaluation process across the delivery system. Participants’ experience and process outcome metrics will drive ongoing refinement and maturation of the process.
Process and Responsibilities

- **Physician Champion** submits proposal to SL Clinical Committee
- **Service Line Clinical Committee** reviews and submits to VAT
  - **New Procedure?**
    - **Yes**
      - Value Analysis Team (VAT) engages Emerging Technology Committee, MEC
    - **No**
      - **Clinical Evidence Accepted?**
        - **Yes**
          - NPC reviews financial impact for PDS and PMG
        - **No**
          - **NPC review clinical evidence**
  - **NPC** reviews trial results and updated evidence
  - **VAT** contacts physician champion
- **NPC removes product from the approved list**
  - **Yes**
    - **NPC recommendation**
      - **Approval**
      - **Non approval**
  - **No**
    - **VAT provides analysis on metrics**
    - **Physician Champion plans and executes roll out**
    - **Limited approval with continued evidence collection**
    - **No approval**

**Departments not affiliated with a service line submit directly to the appropriate VAT**
### Additional Roles and Responsibilities

<table>
<thead>
<tr>
<th>Committee</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| New Product Committee (NPC)                                  | • Evidence and Financial review  
• Outcome metric escalations                                   |
| Emerging Technology Committee                                | • Approval of new procedures and privileging  
• Evidence review                                               |
| Health Plan New Technology Committee                         | • Approval of coverage for new procedures  
• Evaluation of Health Plan impact                             |
| Medical Executive Committee (MEC)                            | • Approval of new procedure and privileging  
• Privileging and requirement process                           |
| Owens and Minor Sourcing Specialists                         | • Receipt, validation, and escalation of new product request forms  
• Initial financial impact assessment (> $50k annually)  
• Acquisition cost assessment for financial review  
• Coordination of value analyses  
• Point of Contact for requesting physician                    |
| Service Line Clinical Committees                             | • New procedure and replacement supply approvals  
• Evidence and appropriate use review  
• Appointment of physician champion                             |
| Value Analysis Steering Committee (VASC)                     | • Policy and leadership  
• Performance goals  
• Approvals, denials  
• Conflict resolution  
• Outcome metrics oversight                                     |
| Value Analysis Teams (VAT)                                   | • Coordinate requests/ product review  
• Contract and supply cost “hot spotting”                       |

### Glossary

**Institutional Review Board (IRB)**  
A committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.

**Principle Investigator (PI)**  
The individual who is responsible and accountable for conducting a clinical trial. The PI assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results.

**Value Assessment Teams (VAT)**  
Presbyterian committees focused on securing lowest prices and contracting rates for clinical supplies and services.