

<b>TITLE:</b> Innovative Implantable Medical Device (IMD) and New Technology Product Introduction Process	<b>POLICY DESCRIPTION:</b> Process guidelines for the introduction, evaluation and contract recommendation for IMD's and New Technology Products
<b>PAGE:</b> 1 of 3	<b>TYPE:</b> National Agreements
<b>EFFECTIVE DATE:</b> 8/16/06	<b>REFERENCE NUMBER:</b> HPG.018

<b>SCOPE:</b> All HPG Colleagues in all HPG Departments
<b>PURPOSE:</b> This process will provide for IMD's and New Technology Products to be submitted, reviewed and final determination made regarding contract status.
<b>POLICY:</b> This process pertains to the introduction of new products and IMD's that have been determined by a supplier to possess certain characteristics that improve upon the applicable standard of care resulting in improved clinical outcomes. The basis of this process will be founded upon sound empirical clinical evidence reviewed and confirmed by the appropriate clinical, quality, technical and operational groups to ultimately determine where the product fits into the spectrum of product clinical efficacy and economics.
<b>EXCEPTIONS:</b>
<p><b>DEFINITIONS:</b></p> <p><b>Implantable Medical Device (IMD)</b> – any device that is permanently implanted into the patient. These products are typically referred to as physician preference items. This includes but is not limited to cardiac rhythm management devices, stents, hip and knee prosthesis, spinal implants, trauma related implants, biological growth agents, etc.</p> <p><b>IMD and New Technology Product Form</b> – this form is completed by the manufacturer and requires information be provided related to the product specifications, reimbursement, clinical or technical trial data, expected clinical or technical impact, indications for use, comparative or replaced product details, and any other relevant product information.</p> <p><b>New Technology Product</b> – any device that is not considered an IMD yet claims to offer incremental to revolutionary improvements to existing products available today for an applicable standard of care.</p> <p><b>SCRUBS</b> – The HPG website which provides separate secured areas for both members and vendors. Contract listings; electronic catalog of product descriptions, item numbers and pricing; letters of commitment; rebate and admin fee allocation information; internal audit report findings; announcements; new contract launch packages; TechNet newsletters; PASS newsletters; HPG annual conference information; and other HPG operational offerings and announcements are available on SCRUBS.</p>

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**PROCEDURE:**

- 1) Once an IMD or New Technology Product is identified whether by the manufacturer (contracted or noncontracted) or through provider identification, the manufacturer will be required to complete and return to the Contract Manager the IMD and New Technology Product Form (see **Exhibit DD**). If the IMD or New Technology Form is being provided by a current contracted supplier and the information is not provided in a timely manner, the IMD or New Technology Product will not be eligible for a price premium.
- 2) The Contract Manager will then distribute the IMD and New Technology Product Form to all applicable clinical, technical, quality and operational groups (including reimbursement) for review. Each group is then responsible for assessing the information provided, verifying the information and providing a group specific overview and recommendation on whether to contract for the product, parameters for contracting including any price premiums if warranted, and potential product impact compared to the current standard of care. This review may also include surgeon specific feedback regarding their own use of the product, resulting clinical outcomes data, and surgeon validation of the product claims.
- 3) The Contract Manager will then assimilate this information into a collective overview which is completed on the IMD and New Technology Product Form and then distribute all feedback and findings back to the applicable groups to come up with a final recommendation on a contracting strategy.
- 4) If needed, the Contract Manager will coordinate any conference calls, meetings and product demonstrations for the applicable groups reviewing the product. The manufacturer may or may not be included in these calls, meetings or demonstrations.
- 5) Once a final recommendation has been reached, the Contract Manager will complete the IMD and New Technology Form outlining the final recommendation. All applicable and supporting documentation will be attached to the form. This recommendation is then communicated back to the manufacturer and a general communication including the IMD and New Technology Product Form with attachments will be generated and distributed to all HPG members and involved groups.

Understanding that during the IMD and New Technology Product Introduction Process there exists time sensitive factors and many of these products may have already been introduced to the market, the product may be placed in a temporary contract status with a mutually agreed upon price or a price not to be greater than existing products of similar intent to ensure the product is available to HPG members. This temporary status will be limited to not more than 180 days. Once the IMD and New Technology Product Introduction Process has been completed and a final recommendation reached,



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the product will be removed from temporary contract status and placed in a status commensurate with the final recommendation. If the final recommendation indicates maintaining a contracted status for the IMD and New Technology Product and indicates an incremental (or “evolutionary”) improvement over existing products of similar intent, then pricing may include a mutually negotiated and agreed upon price premium not to exceed five percent (5%) of pricing for existing products of similar intent. If the IMD and New Technology Product indicates a significant (“revolutionary”) improvement over existing products of similar intent, then pricing will be mutually agreed upon. If agreement on pricing cannot be reached, then the product will be moved to a noncontracted status. In any event, the final status will be communicated back to the manufacturer and all HPG members.

All IMD and New Technology Products submitted will be tracked relative to submission date, products involved, review groups, completion dates and status summary (see **Exhibit EE**). This information will be available to HPG members as a reference through SCRUBS.

**REFERENCES:**

**NOTE:**

A copy of this policy will be maintained on the HPG public website. If you are a bidder and have a question related to the process, please first complete and submit the on-line **Prospective Vendor Request Form** located under the “Supplier” tab of the website.