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From: s 47F
Sent: Wednesday, 15 April 2020 9:44 AM
To: s 47F
Cc: Keaney, Megan; s 22 ; PLAC
Subject: PLAC paper - Fibrin Sealants [SEC=No Protective Marking]
Attachments: 20200414 Evicel report for PLAC CM BH.docx

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I hope you are well. As discussed at the previous PLAC meeting, please find attached a paper for consideration at the upcoming meeting regarding Fibrin Sealants.
I ask that you consider:

- Placing this paper on the agenda for the upcoming meeting, and
- Providing a copy of the paper to the two manufacturers to seek a response prior to the meeting.

Happy to discuss, and department staff, please let me know if you would like the paper to be reformatted,
Thanks

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Fibrin sealants: conditional listing

Recommendation:

- Fibrin Sealants be limited on the Prostheses List to
  - vascular procedures,
  - neurological procedures, or
  - where the surgeon certifies that control of bleeding by conventional surgical techniques is ineffective or impractical.
- The codes to be captured by this conditional listing include
  - MN202, MN203, MN204 (Evicel)
  - BX214, BX215, BX216 (Tisseel)
  - BX283, BX284, BX285 (Artiss)

Key points:

- Fibrin Sealants (Tisseel, Artiss and Evicel) are glues designed to be used in surgeries such as aortic or neurological procedures.

- Both manufacturers describe the products to be used when control of bleeding by conventional surgical techniques (such as suture, ligature and cautery) is ineffective or impractical.

- There has been an average 21% annual increase in these products since Evicel was introduced to the Prostheses List in 2012-13.

- The growth has predominantly been in the area of orthopaedic surgery, where conventional surgical techniques (such as suture, ligature and cautery) are effective and practical.

- The use of Evicel in knee reconstructions has increased the cost by approximately 28%, with no evidence of improved patient outcomes.

- In one instance, more than $10,000 of fibrin sealant was used in a single knee replacement surgery.

- Fibrin sealants were placed on the Prostheses List for a particular purpose, and they are being used for another purpose which has not been subject to a health technology assessment.

- Prostheses List benefits for fibrin sealants should be limited to the manufacturers' intended uses, or when the treating surgeon expressly certifies that they could not use traditional sealing methods.

Background

Fibrin sealants (glues) comprising active components of clottable protein and human thrombin were first used in 1991 in Germany and were approved for use in Australia in 2002.

Consistent to Baxter's packet leaflet:

TISSEEL is used as a supportive treatment when conventional surgical methods appear to be insufficient: - to improve hemostasis - as tissue glue, to improve wound healing or to seal sutures in vascular surgery and in the gastrointestinal tract, in procedures in the nervous system and in surgical interventions where contact with cerebrospinal fluid or the dura mater is possible (e.g. in ENT, ophthalmic and vertebral surgery). - for tissue gluing, e.g. for attaching skin grafts

The indications of usage from the two manufacturers are reproduced below.

----------INDICATIONS AND USAGE----------

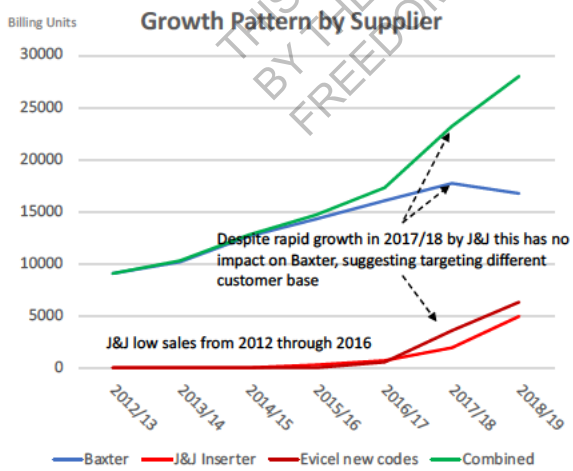
Hemostasis: TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in adult and pediatric patients (>1 month of age) undergoing surgery when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. TISSEEL is effective in heparinized patients.(1.1)

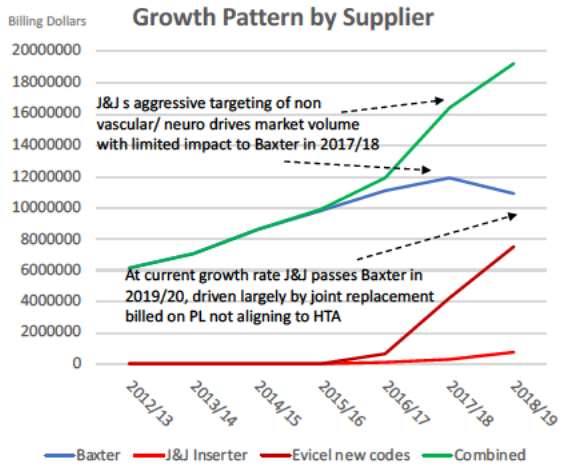
----------INDICATIONS AND USAGE----------

EVICEL® is a Fibrin Sealant (Human) indicated as an adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical (1).

The exclusive supplier of Fibrin Sealant for over a decade was Baxter with Tisseel and later Artiss products (3 sizes of each) listed under 03.08.02 General & Miscellaneous – Closure Devices – Internal Adhesives.

In late 2012 Johnson & Johnson (J&J) had their Evicel product registered on the ARTG and corresponding sales on the PL from 2012/13. Sales for Evicel were minimal through to 2017/18 when a marked increase was observed. While the original Product code is no longer visible on the PL the unit sales for the consumable tip are, supporting limited uptake until 2017/18 (refer graph). J&J now have their 3 sizes spread across two clinical groups. The larger size is in General and Miscellaneous – Closure Devices, with the two smaller sizes listed under 04.02 Neurosurgical Dura Defect (where they attract a higher reimbursement than their Tisseel and Artiss equivalents).





Under a normal commercial situation when a second player enters a mature monopoly market two scenarios are seen, the first is the new player is blocked by the incumbent dominant supplier (what appears to have occurred through 2017, with Evicel unit sales low) or secondly the market is shared in some ratio between both companies. What was observed was a rapid rise of J&J Evicel, five years

after TGA approval and without erosion of share from Baxter in the first 12 months. This made PHI funds suspicious around a possible change in market strategy to deliver growth.

Two questions are asked, where is that growth coming from? And similarly why with a technology that has been in use for over 15 years is it accelerating when surgeries are growing at ~3% annually.

	Baxter	J&J	Combined
2012/13	$6,165,287	$888	$6,166,175
2013/14	$7,116,571	$4,736	$7,121,307
2014/15	$8,630,210	$15,540	$8,645,750
2015/16	$9,860,497	$55,796	$9,916,293
2016/17	$11,090,359	$797,769	$11,888,128
2017/18	$11,902,103	$4,487,884	$16,389,987
2018/19	$10,965,620	$8,304,134	$19,269,754
CAGR	**10.1%**	**359.0%**	**20.9%**

Given the indication for both devices is the same as is their fundamental composition, it would be assumed on a large installed base of users (15 years) with Baxter that J&J's utilisation pattern should be similar. The data suggests the opposite with a very high weighting to the largest volume/price billing code.

Largest size 10ml @$1,295	% of $ Sales	% of units
J&J Evicel	86.7%	79.9%
Baxter Tisseel & Artiss	29.0%	14.6%

In light of the rapid growth of Evicel, with limited competitive erosion to Baxter and the inconsistent usage of ostensibly identical devices PHA undertook a review with a major health fund of the MBS items in which Tisseel and Evicel were used/billed under.

A summary of this data found:

- Baxter's utilization was predominately in vascular operations (Cardio-Thoracic) and Dura Closure.
- For Evicel code MN202 (PL grouped for Dura Defect) 13 Surgical billings had been funded, none were for Neurosurgery, the most common use Orthopaedics
- For Evicel code MN203 (also grouped as Dura Defect) 551 billing events occurred (624 units of MN203), For every recorded Neuro MBS procedure 19 were recorded for Orthopaedics.
- For Evicel code MN204 (grouped under General Miscellaneous) 862 procedures were recorded (1,118 billing events @$1,295 + inserter), none involved Neurosurgery and the most common event was Orthopaedics 638 of the 862 procedures.
- Average cost of Evicel for cases involving MN204 was $1,871.55 (effectively a 28% increase to the cost of a Total Knee Replacement). The inclusion of Dermabond Prineo in many procedures indicated a ~30% increase in device cost from General & Miscellaneous items added from J&J when used in the last 3 years to routine TKR and THR surgery.
- When looking at Cardio Thoracic MBS items, 92.2% of the sales recorded in Fibrin Sealants were from Baxter. By contrast 85% of the use of Fibrin Sealants in Orthopaedics came from J&J.
- One fund member had 8 units of MN204 injected in them at a cost of $10,360 and $1,184 in inserter cost for a combined Evicel cost of $11,544 in a joint replacement procedure, where the genuine implant costs of the joint replacement was under $7,000.

The approved TGA indication for Evicel is large Vascular Surgery and Dura Mater closure. Similarly the IFU states that the product is indicated where control of bleeding by standard surgical technique (such as suture, ligature or cautery) is ineffective or impractical. With over 60 years of joint replacement being performed using a combination of Suture, tourniquet cuffs and cautery it cannot be argued that joint replacement needs or warrants products such as Evicel or Tisseel. No HTA would ever indicate it to be cost effective against suture (already funded under existing hospital and fund agreements and DRGs).

In addition to the aforementioned lack of appropriate utilization, PHA reviewed the price for the largest size of Evicel against the single unit UK NHS list price and found it to be £444.48. We would expect the NHS has tight conditions upon Evicel's use to appropriate vascular/neuro indications.