This paper presents the opinion of Dr. Craig E. McCoy, DO FACOG FPMRS. Bovie Medical Corporation's J-Plasma electrosurgical generators and hand pieces are indicated for the delivery of helium gas plasma to cut, coagulate, and ablate soft tissue during open and laparascopic surgical procedures. The safety and effectiveness of J-Plasma for the treatment of endometriosis has not been established. Dr. McCoy is a paid consultant to Bovie Medical Corporation.

White Paper

THE ECONOMICS OF TREATING FEMALE CHRONIC PELVIC PAIN

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Introduction

Disease population and costs with the changing financial landscape of healthcare

Chronic pelvic pain affects 15-20% of reproductive-age women, creating direct healthcare costs of 2.8 billion annually. ^{1,2,3} Endometriosis is one of the most common gynecologic disorders and is found in 70 – 90% of patients with pelvic pain symptoms. ⁴ Endometriosis is defined as the presence of endometrial-like tissue outside the uterus, which induces a chronic, inflammatory reaction. Although a direct correlation of endometriosis as a significant cause of pelvic pain is inconclusive, research supports severe intensity of pain reported by patients with deep penetration (>_ 6mm below peritoneal surface) of endometriosis. ⁵ This white paper explores the economics of treating endometriosis and its ripple effect to patients, providers, and hospitals.

Endometriosis affects an estimated 1 in 10 women during their reproductive years, which are approximately 176 million women in the world. Assuming a prevalence rate of 10%, and the rates would be much higher if the entire disease population were diagnosed and treated, endometriosis was estimated to cost about \$22 billion in the US during 2002, \$5.9 billion of which were indirect costs due to loss of productively. Of the remaining 16.1 billion, 90% was attributed to hospital care. Hospitalizations were the most significant cost driver, totaling \$12,644 per patient among those who were hospitalized in 2002.

The new reality in healthcare focuses on providing the highest quality patient outcomes at the lowest cost. The Tax Relief and Healthcare Act of 2006 broadly accelerated the transformation of hospitals and healthcare providers to value-based healthcare delivery. In this new realty, providers must leverage innovation to support improved cost effective clinical outcomes. Reimbursement is and will continue to be tied to clinical outcome measures and overall patients' performance; and providers can anticipate revenue reductions. The revenue reductions may occur as a result of decrease in patient volumes, as insurers direct to quality providers, or as a result of reduced payment for services.

The Economic Challenge

The projected increase of patients with endometriosis will prove to be an economic challenge to both hospitals and providers. As reimbursement based on clinical-quality outcomes gains throughout the insurer community, the limitations of current surgical devices and procedures for endometriosis requiring one or more subsequent services, resulting in less than optimal outcomes for the patient, is less than ideal for providers and hospitals.

Balasc and Murphy found that random biopsy samples of grossly normal peritoneum endometriosis patients detected disease in 11% to 25% of biopsies. ^{9,10,11} According to Evers¹², literature data show endometriosis relapse follows a highly predictable course irrespective of the way recurrence was diagnosed; 10% of patients appear to have redeveloped signs and symptoms of endometriosis after one year follow-up period, 25% after three years, and 45% after five years. This high rate of relapse and recurrence, indicative of today's endometriosis interventions, are poor quality patient outcomes.

Reimbursement for procedures using surgical devices will trend to more of "fixed" or bundle payment methods under the value-based reimbursement models. Neither of today's common payment models, capitation and feefor-service (FFS), directly reward improved value of healthcare. The payment approach that seems best aligned with value is a bundled payment. Bundled reimbursements generally coincide with a defined period of time for chronic or acute medical conditions. Reimbursements are coupled to overall care for a patient, aligning payment with what providers can control. Providers can benefit from improving efficiency of care while maintaining or improving patient clinical outcomes.

As bundled payment models burgeon, the way in which care is delivered should also be transformed. Specific to the treatment of endometriosis, surgeons will need access to innovation to offer women with chronic pelvic pain that have failed conservative measures a safe and precise operative treatment. Standalone diagnostic procedures will inherently add costs with little benefit to patients or the new value-based health system.

As the healthcare industry transitions from a volume-based model to a quality outcomes, or value-based model of reimbursement, clinically proven and affordable innovation along with overarching cost-cutting strategies are and will continue to play a bigger role in hospital- and physician-directed healthcare delivery decisions. The need exists for innovative surgical options that aggressively treat all forms of endometriosis while delivering safe, effective, and long lasting patient outcomes.

The Solution

J-Plasma® from Bovie Medical Corporation is a new FDA-cleared electrosurgical device harnessing the power of helium gas plasma for precise and controlled treatment of diseased tissue. This groundbreaking surgical solution offers an all-in-one toolkit for surgeons to probe, scalpel, fulgurate, coagulate, dissect, and paint diseased tissues in continuous or pulsed modes, without grounding pads, eye protection, wet surgical drapes, or calibration procedures. The use of nonconductive currents limits direct injury and tissue spread, reducing the risk of direct and capacitive coupling. Additionally, J-Plasma allows for excision or ablation of endometrial implants with controlled precision and reduced fear of injury to adjacent vital structures. With virtually no thermal flow or collateral tissue damage, surgeons are afforded a new, innovative surgical tool for tackling chronic pelvic pain.

I have perfected a broader, gradated surgical approach with J-Plasma that targets apparent, deep, and occult diseased tissue along the pelvic lining and ligaments. J-Plasma's short learning curve and ease of use allows me to treat visible and microscopic disease tissue, including prophylactic treatment of the uterosacral ligaments and cul-de-sac, safely and with much less risk.

Bovie's innovative device gives me and other surgeons' the ability to confront all stages of endometriosis diseased tissue and address recurrence and relapse for improved patient outcome at a lower cost than other available devices.

The Result

The new healthcare reality demands opportunities to better serve the over 8 million endometriosis sufferers while making economic sense to patients, surgeons, and hospitals.

Patients – a more effective treatment with positive outcomes

Today, endometriosis specialists recognize early treatment of endometriosis using an operative intervention retards the disease's progression towards more advanced stages, which includes profound patient suffering and loss in societal productivity. J-Plasma's innovative feature set allows providers to effectively localize removal of diseased tissue with minimal impact to surrounding healthy tissue.

My laparoscopic surgical method using J-Plasma ablates visible and occult tissue, at the source and regardless of location, has so far reduced the need for subsequent surgeries. Additionally, this targeted treatment of endometriosis and resultant chronic pelvic pain has shown to improve patient outcome in my practice. In a recent nine-question surgical satisfaction questionnaire of 26 chronic pelvic pain and endometriosis patients treated with J-Plasma, 21 reported decreased post-op pain within 12 months. In fact, 85% respondents were satisfied/very satisfied with how their pain was controlled immediately after the surgery, both in the hospital and at home. Most patients (77%) were satisfied with the surgical results with 96% recommending this surgery to someone else and 88% indicating they would do the surgery again. No complications were reported in the group.

Additionally, survey results indicate this precision decreases complications and reduces healing time, which patient experience as overall low 'downtime.' A vast majority of the women surveyed (92%) were satisfied with the amount of time it took to return to work or their normal exercise routine and 88% were satisfied with how long it took to return to their daily activities in and outside the home.

Providers – an advanced treatment, improved economy

The economic climate in healthcare mandates providers to effectively improve clinical outcomes. Streamlining costly surgeries using a groundbreaking laparoscopic intervention economically benefits both the patient and provider. Traditionally, patients with pelvic pain undergo a diagnostic laparoscopy and then, with the disease confirmed, progress to an operative laparoscopy. With endometriosis being the most common cause of patients with pelvic pain symptoms, J-Plasma provides a safe option for prophylactic treatment of confirmed and occult disease through operative laparoscopy.

Relative Value Unit (RVUs) reflects the level of time, skill, training and intensity required of a physician providing a given service. RVUs are a method for calculating the degree of work or effort expended by a physician in treating patients. The opportunity to use innovation such as J-Plasma, as clinically appropriate, can provide for transition from diagnostic laparoscopy to operative laparoscopy. This advanced intervention by providers, when patients demonstrate need for lesion removal, is more effective and less risky for the patient, is fiscally efficient to payers, and allows for incremental RVU for increased physician output. Table 1 shows estimates of a practice that sees an average of 75 women seeking gynecological (GYN) services per week. Table 2 provides Professional Component Allowable comparison by commercial insurers. A comparison between diagnostic and operative laparoscopy services is shown in Table 3.

Table 1: GYN Services Estimate

General GYN

6 million women in US with endometriosis 25% occult endometriosis disease = 7.5 million 33,625 general gynecologists 7.5/33,625 = 223 per provider

Minimally Invasive Specialist

250 OB/GYN residency programs 2 private practices per stage average Total = 350 7.5/350 = \$21,428.75 per provider

Table 2: Professional Component Allowable Comparison

Diagnostic laparoscopy 49320				
Healthlink	\$519.00			
UMR	\$399.00			
BCBS	\$354.00			
HCUSA	\$197.00			
Care Impro	\$258.00			
Operative Laparoscopy 58662				
Healthlink	\$726.00			
UMR	\$701.00			
BCBS	\$925.00			
HCUSA	\$598.00			
Care Impro	\$688.00			

Table 3: Comparison of Professional Services

CPT Code	Procedure	Work RVU	Practice (Non Facility Settings) RVU	Practice (Facility Settings) RVU	Malpractice RVU	Global Days
49320	Diagnostic Laparoscopy- Abdomen	5.14	3.21	3.21	1.03	10
58662	Operative Laparoscopy- laparoscopy excise lesions	12.15	6.33	6.33	1.73	90

Hospitals – a solution for optimal clinical outcomes

In my practice, J-Plasma offers a more effective treatment with an economical solution to current surgical options for the laparoscopic intervention and treatment of endometriosis to hospitals.

The use of J-Plasma enables facilities to optimize clinical outcomes associated with diagnostic/operative laparoscopy and better use of Operating Room (OR) time and resources in increasing incremental OR and hospital revenues. Equipment costs are less with J-Plasma than other available devices. A comparison of average pricing for laparoscopic hand pieces available in the marketplace is presented in Table 4. Additionally, J-Plasma does not require supplies or extra set-

Table 4: Laparoscopic Hand Piece Average Pricing^a

Hand Piece	Average Hand Piece Price
J-Plasma	\$375.00
CO2 Laser	\$600.00
Argon Plasma (ABC)	\$525.00
PlasmaJet	\$550.00

^aPrices vary based on hospital contact and this represents an estimate.

up and maintenance procedures common with other electrosurgical equipment providing a reduction in overall costs. Table 5 provides a cost analysis of the total cost of laparoscopic hand pieces.

Table 5: Average Total Cost of Laparoscopic Hand Piece b

	J-Plasma	CO2 Laser	Argon Plasma (ABC)	PlasmaJet
Cost per Hand Piece:	\$375.00	\$600.00	\$525.00	\$550.00
Cost for number of cases per month: 30	\$11,250.00	\$18,000.00	\$15,750.00	\$16,500.00
Total Cost for 12 months	\$135,000.00	\$ 216,000.00	\$189,000.00	\$198,000.00
Savings with J-Plasma per year:		\$81,000.00	\$54,000.00	\$ 63,000.00

^bPrices vary based on hospital contact and this represents an estimated savings.

With the simplification of equipment, facilities have more options to move operative laparoscopies to an outpatient environment. Table 6 presents compared data on facility reimbursements for laparoscopic procedures demonstrating benefits to providers, and hospital/surgical centers.

Finally, in my experience, the innovative improvement in precision with J-Plasma for addressing sensitive tissue allows for less complicated postoperative recovery, and in many cases expedited discharge due to the less invasive care resulting in increased patient throughput and reduced facility expenses.

Conclusion

The role and value of medical innovations are paramount to providers, hospitals, and patients as the current healthcare system evolves to value-based models. While the rate of change to majority value-based reimbursement across commercial and government insurers is unknown, adoption of innovations like J-Plasma for the treatment of

Table 6: Facility Reimbursement Data

49320 - Abdomen, laparoscopic, diagnostic				
Inpatient Setting				
Average Medicare Payment	\$2,922.00			
Average Insurance Payment	\$5,416.00			
Outpatient Setting				
Average Medicare Payment	\$2,922.00			
Average Insurance Payment	\$4,264.00			
58662 - Ovary, pelvic or peritoneal lesion removal, laparoscopic				
Inpatient Setting				
Average Medicare Payment	\$4,628.00			
Average Insurance Payment	\$7,628.00			
Outpatient Setting				

Grand Rapids, MI Metropolitan Service Area for demonstration purposes

Average Medicare Payment

Average Insurance Payment

\$4,628.00

\$5,400.00

endometriosis enables all stakeholders to meet current and future economic challenges. J-Plasma allows me and other providers a progressive surgical alternative to treating all stages of endometriosis; affords hospitals a lower cost to current surgical options in the laparoscopic intervention and treatment of endometriosis; and offers significant improvements in the quality of life and disease comorbidities of affected women. I consider J-Plasma to be an emerging advantage in the preparation of clinical quality services essential to the value-based healthcare model.

Coding and reimbursement information is provided for informational purposes only. This content is not intended to instruct medical providers on how to bill for healthcare procedures or to describe proper coding, billing, and payment levels.

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