

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

**Tracking Form for Applicants for New Technology Add-on Payments  
under the Acute Inpatient Prospective Payment System (IPPS) for  
Federal Fiscal Year (FY) 2009**

1. Technology Name: Intra-operative Gel

2. Manufacturer Name:

FzioMed, Inc.  
231 Bonnetti Drive  
San Luis Obispo, CA 93401  
805-546-0610

3. Trade Brand of Technology: Oxiplex®

4. Brief Description of Service or Device:

Oxiplex is an absorbable viscoelastic gel made of carboxymethylcellulose (CMC) and polyethylene oxide (PEO) that is surgically implanted during a posterior discectomy, a laminectomy or laminotomy and is indicated for the reduction of pain, radiculopathy, and lower extremity weakness and incidence, extent and severity.

Oxiplex is used as an adjunct to surgery to provide a protective environment around the nerve root and dura during the healing process. Oxiplex reduces nerve root and neural tissue exposure to fibrin, wound exudates, neurotoxins and pro-inflammatory mediators that can cause pain and neurological symptoms post surgery.

**New Criteria**

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

Expected approval: March or April 2008

The FDA has granted Oxiplex expedited review because there are no other approved products that reduce pain and symptoms following lumbar surgery. Because Oxiplex has not been approved, nor are there other approved products on the market, there are no claims data to support payment in the DRG system.

The mechanism of action of Oxiplex is also different than previously approved devices. Oxiplex is an inactive agent that creates a protective environment to limit

nerve root exposure to post-surgical damage and irritation (by neurotoxins, cytokines). By protecting the nerve root, Oxiplex reduces post surgical pain and neurological symptoms.

The 352 patient US IDE study was designed to show a reduction in back and leg pain, including associated neurologic symptoms, due to a posterior discectomy, laminectomy, or laminotomy. This is a new and different indication for any US products.

6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation for any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

The product is not yet FDA approved.

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

An application for a new ICD-9-CM code was presented at the September 2007 Coordination and Maintenance committee meeting. The results are pending.

- a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.
- b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to [http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01\\_overview.asp#TopOfPage](http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage) for more information.) We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment.

An application for an ICD-9-CM code is pending.

8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking

No, a pass through application has not been submitted.

**(For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage)) Note: The information provided on this tracking form will be made publicly available. (For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage)) Note: The information provided on this tracking form will be made publicly available.**

number or, if it was approved, please provide the date of approval. (Please refer to [http://www.cms.hhs.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp#TopOfPage](http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage) for more information.)

## **Cost Criteria**

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by DRG. The most recent version of Table 10 can be downloaded at: [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

Oxiplex can be used in posterior discectomy, laminectomy or laminotomy cases. The associated ICD-9-CM codes are: 03.09 “other exploration and decompression of spinal canal” decompression: laminectomy, laminotomy and 80.51 “excision of intervertebral disc” discectomy, cervical, thoracic or lumbar.

Below is the MedPar data for 2006 showing average charges for DRGs 499 and 500 with each of these ICD-9-CM codes. Starting in October 2007, these ICD-9-CM codes will be grouped into DRGs 490 and 491. Therefore the Table 10 Threshold Charges reflect DRGs 490 and 491. For additional details on the Cost Criteria evaluation see the New Technology Add-On Payment Application.

**Table I**

| <b>DRG</b>                         | <b>Total Standardized Charges per case</b> |
|------------------------------------|--|
| <b>Cases with 03.09 in DRG 499</b> | \$35,354                                   |
| <b>Cases with 03.09 in DRG 500</b> | \$26,466                                   |
| <b>Cases with 80.51 in DRG 499</b> | \$32,090                                   |
| <b>Cases with 80.51 in DRG 500</b> | \$24,565                                   |

**\*2006 MedPar Data**

9. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology, clearly showing which components are the “new” ones).

The Charge for Oxiplex was calculated by using the average cost-to-charge ratio (CCR) for the supplies shown in the MedPar data in Tables II and III (New Technology Add-On Payment Application).

10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

DRG 490 or DRG 491

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2009 (by DRG)?

New Technology Add-On Payment Application

### **Clinical Improvement**

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

Oxiplex was studied under IDE (#G000226). Results from the clinical trial are listed below. In addition to showing a statically significant reduction in leg pain the Oxiplex group only had one revision versus six revisions with the control group.

- The primary effectiveness outcome of improvement in leg pain at 1 month, 3 months and 6 months showed a statistically significant interaction between treatment and baseline back pain in the Intent-to-Treat (ITT) population ( $P=0.0113$ ) in subjects having severe baseline back pain.
- Subjects with severe back pain at baseline showed significantly greater improvement (reduction from baseline) in leg pain in the Oxiplex group compared to subjects in the Control group. A subgroup analysis confirmed the interaction over all visits ( $P=0.0267$ ) in subjects having severe baseline back pain.
- Of the seven re-operations, only one involved a subject from the Oxiplex group.

- Other analyses revealed that fewer Oxiplex subjects were receiving physical therapy at 90 days ( 37.2% versus 47.2%) and fewer Oxiplex subjects were receiving narcotics at 90 days (18.6% versus 24.2%).

b. List all published peer-review articles relevant to the new service or technology.

KD Kim, JC Wang, DP Robertson et al, Reduction of Radiculopathy and Pain with Oxiplex/SP Gel after Laminectomy, Laminotomy, and Discectomy, Spine 2003, Vol 28, Number 10, pp 1080-1088.

KD Kim, JC Wang, DP Robertson et al, Reduction of Leg Pain and Lower Extremity Weakness for 1 Year with Oxiplex/SP Gel after Laminectomy, Laminotomy, and Discectomy, Neurosurg Focus 2004, Vol 17, Number 1, pp 1-6.