NUVECTRA™

Our specialists are dedicated to supporting your team with all aspects of pre-authorization processes, case management, and reimbursement matters. We understand that patients come first, that's why we ensure current coding and procedure resources are readily available to support your efforts in providing access to therapy.

We have taken this opportunity to provide you with a Pre-Authorization packet containing required paperwork for each case as well as sample letters of medical necessity and candidate clearance. The intent of this guide is to ease you through preparation of the patient's case. However, should you have preliminary questions, our team is available from 7am to 6pm CST to assist. Enclosed:

- **List of required paperwork by payor for authorizations attached to case information form**
- **Certificate of medical necessity**
- **Patient Questionnaire and Release (HIPAA) or copy used by physician's office**
- **Medicare medical policy guidelines**
- **Sample: Letter of Medical Necessity**
- **Sample: Psychiatric Clearance for SCS**
- **Business Associate Agreement**

Welcome to Nuvectra! We look forward to improving your solutions for patient needs.

Nuvectra™ Connect
Pre-Authorization Specialists

Nuvectra™ Connect | Pre-Authorization
5830 Granite Parkway, Suite 1100
Email: preauth@nuvectramed.com
Phone: 1-844-727-7897

NUVECTRA™

Nuvectra™ Pre-Authorization Packet | Cover Sheet

Please send the documentation listed below with the case information form.

Medicare

- Case information form
- Copy of Medicare and any supplementary policy cards
- Signed patient release of records
- Medicare-approved diagnosis (as listed in policy)
- Current psychological evaluation report
- Onset date of pain or treatment of pain

Workers' Compensation

- Case information form
- Signed patient release of records
- Workers' compensation contact information (Adjustor Name, Number, Claims Address)
- Claim Information
    - Date of injury
    - Employer and claim number
    - State where injury occurred
- Clinical information (past 6 months)
    - Documentation related to the compensable injury
    - Letter of medical necessity
    - History and Physical
    - Previous treatment notes
    - Diagnostic test reports
    - Physical Therapy notes

Nuvectra™ Connect | Pre-Authorization
5830 Granite Parkway, Suite 1100
Email: preauth@nuvectramed.com
Phone: 1-844-727-7897

NUVECTRA™

Private Insurance

- Case information form
- Signed patient release of records
- Copy of insurance card(s) with phone numbers and claim address
- Current psychological evaluation
- Clinical information (past 6 months)
    - Letter of medical necessity
    - Current office visit notes
    - History and physical
    - Previous treatment notes
    - Diagnostic test reports
    - Physical Therapy notes

Self/Private Pay

- Case information form
- Signed patient release of records
- Contact number for payer

Please contact Nuvectra™ Connect for support with your Pre-Authorization process.

NUVECTRA™

Nuvectra Pre-Authorization Packet | Case Information Form

Please complete and send this form to the Pre-Authorization Specialists with Nuvectra Connect via fax (972-695-4031) or email preauth@nuvectramed.com

Patient Information	**Patient:**	**Date of birth: (mm/dd/yyyy)**	**Phone number:**	
	Street address:	**City:**	**State:**	**Zip:**
Physician Information	**Physician name:**	**Group name:**		
	Street address:	**City:**	**State:**	**Zip:**
	Phone number:	**Fax number:**		
	Tax ID number:	**Physician NPI:**		
Procedure Information	**Surgery Date:**	**Primary ICD-10 (required):**	**Secondary ICD-10:**	**Therapy (select from list):**
				SCS (Spinal Cord Stimulatic
	Procedure planned (select or check box):			
	Select One	**Trial** ☐ **Perm** ☐	**Replacement** ☐	**Revision** ☐
	CPT codes:			
Place Of Service	**Name:**	**Location type (select from list:)**		
		Select One		
	Phone number:	**Fax number:**		
	Street address:	**City:**	**State:**	**Zip:**
	Tax ID number:	**Facility NPI:**		
Primary Coverage	**Check all that apply:**	**Benefits** ☐	**Pre-auth** ☐	**Pre-determination** ☐
	Payor:	**Payor type (select from list):**	**Policy number:**	
		Select One		
	Phone number:	**Fax number:**	**Group number:**	
Secondary Coverage	**Payor:**	**Payor type (select from list):**	**Policy number:**	
		Select One		
	Phone number:	**Fax number:**	**Group number:**	
Worker's Compensation	**Employer:**	**Date of injury:**	**Claim #**	
	Adjustor's name:	**Phone number:**		
	TM assigned:	**Office contact email:**		

**A pre-deterimation is an optional review in which the payer will analyze the payer's benefits to see if he/she has coverage for the therapy requested. pre-determination reviews often take longer than prior authorization reviews, typically 15-30 days.

Information provided by Nuvectra is for illustrative purposes only and does not constitute coding, reimbursement or legal advice. It is always the provider's responsibility to determine the medical necessity and proper site of service for the procedure, and to submit appropriate codes, charges and modifiers for services rendered.

NUVECTRA™

Nuvectra™ Pre-Authorization Packet | Medical Necessity Certificate

Certificate Document 1 of 3

Valued Physician,

Please find attached a template for the certificate of medical necessity. This template includes commonly used CPT (procedure) and HCPCS (equipment) codes for spinal cord stimulation. Payors often request this information be provided for a pre-authorization request or claim submission. Most payors will accept this form.

The form also includes a list of commonly used ICD-10 diagnosis codes for spinal cord stimulation. This is meant to be a generalized guide for codes indicating neuropathic pain. Medicare and many insurance companies generally accept these codes. However, please keep in mind that ICD-10 codes are updated annually, so this list is only valid for the year 2016.

This reference is provided for information purposes only. It does not serve as reimbursement or legal advice, nor is it intended to increase payment by any payor. Nothing in this reference guarantees that the levels of reimbursement, payment, or charges are accurate or that reimbursement will be received. The physician or provider is responsible for obtaining reimbursement and for verifying the accuracy and veracity of all claims submitted to third-party payors. Laws, regulations, and coverage policies are complex and updated frequently, and therefore physicians and providers should consult their local carriers, administrative contractors, or a reimbursement specialist with reimbursement or billing questions.

This document is intended to provide reimbursement assistance only where products have been used according to their FDA approved or cleared indications. Where reimbursement is being requested in conjunction with use of a product that is inconsistent with, or not expressly granted in, the FDA approved labeling (which may be found in the clinician's manual, user's guide, or directions for use), please consult your billing personnel or the payor for instructions on the proper handling of this type of claim. Some payors may restrict such claims or services. Contact your Medicare contractor or other payor for any questions regarding coverage, coding, and payment.

Please feel free to contact Nuvectra™ Connect Pre-Authorization Specialists with any questions you may have regarding the attached template.

Thank you,

Nuvectra™ Connect Pre-Authorization Team

Nuvectra™ Connect | Pre-Authorization
5830 Granite Parkway, Suite 1100
Email: preauth@nuvectramed.com
Phone: 1-844-727-7897

NUVECTRA™

Nuvectra™ Pre-Authorization Packet | Medical Necessity Certificate

Certificate Document 2 of 3

Patient Name: _____ Date of birth: _____ Facility: _____

PROCEDURE PLANNED			
Trial of spinal cord stimulation		Neurostimulation IPG replacement	
Neurostimulation implant		Neurostimulation lead revision	
Neurostimulation lead replacement		Neurostimulation IPG revision	
PRESCRIPTION: ORDER FOR NUVECRA NEUROSTIMULATION EQUIPMENT			
Trial lead(s)		Rechargeable implantable pulse generator (patient programmer, charger)	
Trial stimulator		Neurostimulation implant – laminectomy lead(s)	
Neurostimulation implant – percutaneous lead(s)		Extension(s)	
PRIMARY DIAGNOSIS CODES: PLEASE CHECK A PRIMARY (BOLD) & ALL SECONDARY DIAGNOSIS CODES THAT APPLY			
G89.21	**Chronic pain due to trauma**	**G89.4**	**Chronic pain syndrome**
G89.28	**Other chronic postoperative pain**		
SECONDARY DIAGNOSIS CODES			
G03.9	Meningitis unspecified		
Reflex sympathetic dystrophy of the upper limb (CRPS type I of upper limb)		G90.511	Complex regional pain syndrome I of **right** upper limb
		G90.512	Complex regional pain syndrome I of **left** upper limb
		G90.513	Complex regional pain syndrome I of upper limb **bilateral**
		G90.519	Complex regional pain syndrome I of upper limb, **unspecified**
Reflex sympathetic dystrophy of the lower limb (CRPS type I of lower limb)		G90.521	Complex regional pain syndrome I of **right** lower limb
		G90.522	Complex regional pain syndrome I of **left** lower limb
		G90.523	Complex regional pain syndrome I of lower limb, **bilateral**
		G90.529	Complex regional pain syndrome I of lower limb, **unspecified**
G90.59	Complex regional pain syndrome I of other specified site	G57.80	Other specified mononeuropathies of unspecified lowerlimb
G54.0	Brachial plexus disorders	G57.90	Unspecified mononeuropathy of unspecified lower limb
G54.1	Lumbosacral plexus disorders	I70.229	Atherosclerosis of native arteries of the extremities with rest with pain, unspecified extremity
G54.6	Phantom limb syndrome, with pain	M96.1	Postlaminectomy syndrome, not elsewhere classified
G54.8	Other nerve root and plexus disorders	M54.12	Radiculopathy, cervical region
G56.40	Causalgia of unspecified upper limb	M54.13	Radiculopathy, cervicothoracic region
G56.8	Other specified mononeuropathies of unspecified upper limb	M54.3	Sciatica, unspecified side
G56.90	Unspecified mononeuropathy of unspecified upper limb	M54.14	Radiculopathy, thoracic region
G57.70	Causalgia of unspecified lower limb	M54.15	Radiculopathy, thoracolumbar region
B02.22	Postherpetic trigeminal neuralgia	M54.16	Radiculopathy, lumbar region
B02.29	Other Postherpetic nervous system involvement	M54.17	Radiculopathy, lumbosacral region
S14.101A-S14.104A	Unspecified injury at C1-C4 level of cervical spinal cord, initial encounter	S14.111A-S14.114A	Complete lesion at C1-C4 level of cervical spinal cord, initial encounter
S14.131A-S14.134A	Anterior cord syndrome at C1-C4 level of cervical spinal cord, initial encounter	S14.121A-S14.124A	Central cord syndrome at C1-C4 level of cervical spinal cord, initial encounter
S14.151A-S14.154A	Other incomplete lesion at C1-C4 level of cervical spinal cord, initial encounter	S14.105A-S14.108A	Unspecified injury at C5-C8 level of cervical spinal cord, initial encounter

NUVECTRA™

Nuvectra™ Pre-Authorization Packet | Medical Necessity Certificate

Certificate Document 3 of 3

Patient Name: _____ Date of birth: _____ Facility: _____

S14.115A-S14.118A	Complete lesion at C5-C8 level of cervical spinal cord, initial encounter	S14.135A-S14.138A	Anterior cord syndrome at C5-C8 level of cervical spinal cord, initial encounter
S14.125A-S14.128A	Central cord syndrome at C5-C8 level of cervical spinal cord, initial encounter	S14.155A-S14.158A	Other incomplete lesion at C5-C8 level of cervical spinal cord, initial encounter
S24.101A-S24.102A	Unspecified injury at T1 level of thoracic spinal cord, initial encounter. Unspecified injury at T2-T6 level of thoracic spinal cord, initial encounter.	S24.111A-S24.112A	Complete lesion at T1 level of thoracic spinal cord, initial encounter. Complete lesion at T12-T6 level of thoracic spinal cord, initial encounter.
S24.131A-S24.141A	Anterior cord syndrome at T1 level of thoracic spinal cord, initial encounter. Anterior cord syndrome at T2-T6 level of thoracic spinal cord, initial encounter.	S24.151A-S24.152A	Other incomplete lesion at T1 level of thoracic spinal cord, initial encounter. Other incomplete lesion at T2-T6 level of thoracic spinalcord, initial encounter.
S24.103A-S24.104A	Unspecified injury at T7-T10 level of thoracic spinal cord, initial encounter. Unspecified injury at T11-T12 level of thoracic spinal cord, initial encounter.	S24.113A-S24.114A	Complete lesion at T7-T10 level of thoracic spinal cord, initial encounter. Complete lesion at T11-T12 level of thoracic spinal cord initial encounter.
S24.133A-S24.134A	Anterior cord syndrome at T7-T10 level of thoracic spinal cord, initial encounter. Anterior cord syndrome at T11-T12 level of thoracic spinal cord, initial encounter.	S24.153A-S24.154A	Other incomplete lesion at T7-T10 level of thoracic spinal cord, initial encounter. Other incomplete lesion at T11-T12 level of thoracic spinal cord, initial encounter.
S34.109A	Unspecified injury to unspecified level of lumbar spinal cord, initial encounter	S34.3XXA	Injury of cauda equine, initial encounter
S34.139A	Unspecified injury to sacral spinal cord, initial encounter	S14.109A	Unspecified injury at unspecified level or cervical spinal
S24.109A	Unspecified injury at unspecified level or thoracic spinal cord, initial encounter	S34.109A	Unspecified injury at unspecified level or lumbar spinal cord, initial encounter
S14.2XXA	Injury of nerve root of cervical spine, initial encounter	S24.2XXA	Injury of nerve root of thoracic spine, initial encounter
S34.21XA	Injury of nerve root of lumbar spine, initial encounter	S34.22XA	Injury of nerve root of sacral spine, initial encounter
S14.3XXA	Injury of brachial plexus, initial encounter	S34.4XXA	Injury of lumbosacral plexus, initial encounter

MEDICAL NECESSITY – CERTIFICATION THAT THIS PATIENT MEETS THE FOLLOWING CRITERIA

- □ Psychological evaluation if required by payor
- □ Improvement in function is documented in the medical record
- □ Implantation of the stimulation is a last resort for this patient with chronic intractable pain
- □ Patient has undergone careful screening evaluation and diagnosis by a multidisciplinary team prior to implantation
- □ Demonstration of 50% greater pain relief with temporary implanted electrode(s) precedes permanent implantation
- □ The facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, training, and follow-up care of the patient are informed/available
- □ Other treatment modalities (e.g., medication, prior surgery, and physical therapy) have been tried and did not prove to be satisfactory or have been judged unsuitable/contraindicated for this patient

Print physician's name: _____

Physician signature: _____

Date: _____

Nuvectra™ Connect | Pre-Authorization
5830 Granite Parkway, Suite 1100
Email: preauth@nuvectramed.com
Phone: 1-844-727-7897

NUVECTRA™

HIPAA Privacy Authorization Form

**Authorization for Use or Disclosure of Protected Health Information

(Required by the Health Insurance Portability and Accountability Act, 45 C.F.R. Parts 160 and 164)**

1. Authorization

I authorize _____ (healthcare provider) to use and disclose the protected health information described below to _____NUVECTRA___CORPORATION_____ (individual/entity seeking the information).

2. Effective Period

This authorization for release of information covers the period of healthcare from:

a. ☐ _____ to _____.

OR

b. ☐ all past, present, and future periods.

3. Extent of Authorization

a. ☐ I authorize the release of my complete health record (including records relating to mental healthcare, communicable diseases, HIV or AIDS, and treatment of alcohol or drug abuse).

OR

b. ☐Other (please specify): _____

4. This medical information may be used by the person I authorize to receive this information for medical treatment or consultation, billing or claims payment, or other purposes as I may direct.

NUVECTRA™

5. This authorization shall be in force and effect until _____ (date or event), at which time this authorization expires.

6. I understand that I have the right to revoke this authorization, in writing, at any time. I understand that a revocation is not effective to the extent that any person or entity has already acted in reliance on my authorization or if my authorization was obtained as a condition of obtaining insurance coverage and the insurer has a legal right to contest a claim.

7. I understand that my treatment, payment, enrollment, or eligibility for benefits will not be conditioned on whether I sign this authorization.

8. I understand that information used or disclosed pursuant to this authorization may be disclosed by the recipient and may no longer be protected by federal or state law.

Signature of patient or personal representative

Printed name of patient or personal representative and his or her relationship to patient

---

Date

NUVECTRA™

Nuvectra™ Pre-Authorization Packet | Medicare Primary Pain Codes

ICD-10 Codes
G89.0 Pain, not elsewhere classified Code also related psychological factors associated with pain (F45.42) *Excludes: generalized pain NOS (R52), pain disorders exclusively related to psychological factors (F45.42), pain NOS (R52), atypical face pain (G50.1), headache syndromes (G44.-)* *localized pain, unspecified type- code to pain by site, such as:* *abdomen pain (R10.-), back pain (M54.9), breast pain (N64.4), chest pain (R07.1-R07.9), ear pain (H92.0), eye pain (H57.1), headache (R51), joint pain (M25.5-), limb pain (M79.6-), lumbar region pain (M54.4), painful urination (R30.9), pelvic and perineal pain (R10.2), renal colic (N23), shoulder pain (M25.51-), spine pain (M54.-), throat pain (R07.0), tongue pain (K14.6), tooth pain (K08.8), migraines (G43.-), myalgia (M79.1), pain from prosthetic devices, implants, and grafts (T82.84, T83.83, T84.84, T85.84), phantom limb syndrome with pain (G54.6), vulvar vestibulitis (N94.810), vulvodynia (N94.81-)*
G89.0 Central pain syndrome Déjérine-Roussy syndrome myelopathic pain syndrome thalamic pain syndrome (hyperesthetic)
G89.1 Acute pain
G89.11 Acute pain due to trauma
G89.12 Acute post-thoracotomy pain Post-thoracotomy pain NOS
G89.18 Other acute postoperative pain Postoperative pain NOS
R52 Other acute pain *Excludes: neoplasm related acute pain (G89.3)*
G89.2 Chronic pain *Excludes: Causalgia, lower limb (G57.7-)* *causalgia, upper limb (G56.4-)* *central pain syndrome (G89.0)* *chronic pain syndrome (G89.4)* *complex regional pain syndrome II, lower limb (G57.7-)* *complex regional pain syndrome II, upper limb (G56.4-)* *neoplasm related chronic pain (G89.3)* *reflex sympathetic dystrophy (G90.5-)*
G89.21 Chronic pain due to trauma
G89.22 Chronic post-thoracotomy pain
G89.28 Other chronic postoperative pain
G89.29 Other chronic pain
G89.3 Neoplasm related pain (acute) (chronic) cancer associated pain pain due to malignancy (primary) (secondary) tumor associated pain
G89.4 Chronic pain syndrome Chronic pain associated with significant psychosocial dysfunction

This reference is provided for information purposes only. It does not serve as reimbursement or legal advice, nor is it intended to increase payment by any payor. Nothing in this reference guarantees that the levels of reimbursement, payment, or charges are accurate or that reimbursement will be received. The physician or provider is responsible for obtaining reimbursement and for verifying the accuracy and veracity of all claims submitted to third-party payors. Laws, regulations, and coverage policies are complex and updated frequently, and therefore physicians and providers should consult their local carriers, administrative contractors, or a reimbursement specialist with reimbursement or billing questions.

This document is intended to provide reimbursement assistance only where products have been used according to their FDA approved or cleared indications. Where reimbursement is being requested in conjunction with use of a product that is inconsistent with, or not expressly granted in, the FDA approved labeling (which may be found in the clinician's manual, user's guide, or directions for use), please consult your billing personnel or the payor for instructions on the proper handling of this type of claim. Some payors may restrict such claims or services. Contact your Medicare contractor or other payor for any questions regarding coverage, coding, and payment.

NUVECTRA™

Nuvectra™ Pre-Authorization Packet | Letter of Medical Necessity

To whom it may concern,

Please consider this letter as an authorization request for (insert name) to undergo a trial spinal cord stimulation. A trial of spinal cord stimulation is medically necessary to treat this patient with a diagnosis of (insert diagnosis).

(insert name) has undergone careful screening, evaluation, and diagnosis by a multi-disciplinary team prior to this request. He/she has tried other more conservative methods of pain management, including physical therapy, medication trials, interventional procedures such as injections and nerve blocks, behavioral modification, etc. None of these treatment modalities has provided effective, long-term relief of this patient's chronic intractable pain. In addition, this patient is not a surgical candidate.

Spinal cord stimulation therapy uses an implanted, programmable neurostimulator and stimulation leads that deliver small electrical pulses to the spinal cord. This stimulation interrupts or masks the pain signals to the brain. The neurostimulator is implanted beneath the skin and the leads are inserted into the spinal column. Neurostimulation therapies also exist for a number of other conditions, including urinary incontinence, epilepsy, and Parkinson's disease. The difference between the therapies lies in the location of the stimulation lead placement in the body. The objective of SCS therapy is to reduce a patient's pain to a manageable level so that the patient can return to a more normal lifestyle and resume his/her daily activities.

Patients who are candidates for SCS undergo a trial prior to long-term implantation. The trial allows the physician and patient to determine if SCS provides sufficient pain relief to warrant a long-term placement (the standard of care is 50% or greater reduction in pain). During the trial, the patient uses a trial stimulator that is worn outside of the body and is attached to leads by a trial cable. The patient wears the trial stimulator while engaging in normal activities for about a week. During this time, the patient keeps a diary on the effects of the trial on daily life: sleep, activity levels, range of motion, personality, mood swings, and use of pain medication.

The clinical information about spinal cord stimulation demonstrates that insurance coverage is both appropriate and necessary. Successful SCS could mean that (insert name)'s pain would be reduced, and it would possibly allow him/her to be able to resume a more active lifestyle.

Give the treatment methods available, SCS is the most effective choice for treating (insert name)'s pain. Research, clinical studies, and patient outcomes support this recommendation. Therefore, I am requesting your consideration in allowing (insert name) to undergo a trial of spinal cord stimulation to see if it is successful in relieving his/her pain.

Sincerely,

_____

NUVECTRA™

Nuvectra™ Pre-Authorization Packet | Sample Psychiatric Clearance for SCS

To whom it may concern,

I have performed a psychological evaluation on _____. I feel he/she is an appropriate candidate for a trial and/or permanent implant of a spinal cord stimulation system. He/she has no drug addiction or underlying psychological conditions which would adversely affect the outcome of this procedure. In addition, relief from his/her chronic pain may prove therapeutic in relieving some of his/her depressive symptoms.

If you have additional questions, please contact me at _____.

Sincerely,

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the "Agreement") is made and entered into as of this _____ day of_____, 2018 (the "Effective Date"), by and between Nuvectra Corporation ("Nuvectra") and _____ ("Covered Entity"). Covered Entity and Nuvectra may be referred to herein each individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Nuvectra and Covered Entity desire to comply with the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 ("HIPAA"), as amended and supplemented by Title XIII, Subtitle D of the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and the regulations promulgated pursuant thereto, as may be amended from time to time (the "HIPAA Regulations").

WHEREAS, Nuvectra agrees to undertake the responsibilities provided herein if and to the extent that, given the nature of the relationship between Nuvectra and the Covered Entity, Nuvectra is a "Business Associate" of Covered Entity (as defined by HIPAA).

NOW, THEREFORE, in consideration of the foregoing recitations and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows.

AGREEMENT

I. DEFINITIONS

Capitalized terms not otherwise defined in this Agreement shall have the meaning given those terms by HIPAA, HITECH, and the HIPAA Regulations, as in effect or as amended from time to time.

1. "Protected Health Information" or "PHI" shall have the same meaning as the term "protected health information' in 45 CFR 160.103, limited to the information created, received, maintained, or transmitted by Nuvectra from or on behalf of Covered Entity. Covered Entity and Business Associate agree this Agreement does not apply to any patient information that Business Associate receives with a separate patient or practitioner consent, so long and the patient consent is in writing, the patient consent meets the requirements of applicable law, and Business Associate's use of the patient information is limited to uses permitted by the written consent.

2. "Secretary" means the Secretary of the U.S. Department of Health & Human Services.

3. “Security incident” shall have the same meaning as the term “security incident” in the HIPAA regulations, but shall not include trivial incidents that occur on a daily basis such as scans, pings, or routine unsuccessful attempts to penetrate computer networks or servers maintained or utilized by Nuvectra.

4. “Covered Entity”. A Covered Entity is a health plan, health care provider, or healthcare clearinghouse that must comply with the HIPAA Privacy Rule.

5. “HIPAA Regulations”. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy and Security Regulations including, but not limited to, 45 C.F.R. Sections 160.103 and 164.501.

II. OBLIGATIONS OF NUVECTRA

1. Use and Disclosure of Protected Health Information. Nuvectra agrees to nut use or disclose Protected Health Information other than as permitted or required by this Agreement or as Required By Law. Nuvectra may use the PHI received from Covered Entity if necessary for (1) the proper management and administration of Nuvectra (including, for example, providing deidentified authorization results with patient initials to Nuvectra sales representatives for purposes of coordinating appropriate product fulfillment); or (2) to carry out the legal responsibilities of Nuvectra.

2. Safeguards. Nuvectra agrees to implement and use appropriate safeguards to prevent use or disclosure of Protected Health Information bother than as provided for by this Agreement. Safeguards shall include the establishment and maintenance of appropriate administrative, physical, and technical safeguards that are designed to reasonably and appropriately protect the confidentiality, integrity, and availability of PHI (whether electronic or otherwise).

3. Mitigation. Nuvectra agrees to mitigate, to the extent practicable, any harmful effect that is known to Nuvectra of a use or disclosure of Protected Health Information by Nuvectra in violation of the requirements of this Agreement.

4. Access. The Parties do not intend for Nuvectra to maintain any Protected Health Information in a Designated Record Set for Covered Entity. To the extent that Nuvectra maintains PHI for Covered Entity in a Designed Record Set, Nuvectra agrees to provide access to such PHI in a Designated Record Set to Covered Entity upon request by Covered Entity to allow it to comply with Section 164.254 of the HIPAA Regulations.

5. Amendments. To the extent that Nuvectra maintains Protected Health Information for Covered Entity in a Designated Record Set, upon receipt of a request from Covered Entity to amend PHI about an individual contained in such Designated Record Set maintained by Nuvectra, Nuvectra will may any amendment(s) to the PHI in the Designated Record Set that Covered Entity directs.

6. Audit. Nuvectra agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information available to the Secretary upon request for purposes of the Secretary determining Covered Entity's compliance with the HIPAA Regulations.

7. Documentation of Disclosures. Nuvectra agrees to document such disclosures of PHI as would be required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with Section 164.528 of the HIPAA Regulations.

8. Accounting. Nuvectra agrees to provide to Covered Entity information collected in accordance with Section II.7 of this Agreement to permit Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with Section 164.528 of the HIPAA Regulations.

9. Subcontractors and Agents. Nuvectra agrees to ensure that any agent, including a subcontractor, to whom it provides PHI agrees to the same restrictions and conditions that apply through this Agreement to Nuvectra with respect to such PHI.

10. Delegated Obligations. To the extent Nuvectra is to carry out any of Covered Entity's obligations under the Subpart E (the Privacy Rule) of the HIPAA Regulations, Nuvectra shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation.

11. Breaches or Security Incidents. Nuvectra shall report to Covered Entity any Security Incident of which it becomes aware within a reasonable time after Nuvectra discovers such Security Incident. Nuvectra further agrees to notify Covered Entity of any Breach of unsecured PHI, but limited to such unsecured PHI created, maintained, or received by Nuvectra from on behalf of Covered Entity ("Unsecured PHI") without unreasonable delay after discovery of such Breach by Nuvectra. Such notice shall comply with the Breach notification requirements set forth in the HIPAA Regulations and shall include to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by Nuvectra to have been, accessed, acquired, or disclosed during such Breach. Nuvectra shall provide Covered Entity with any other information available to Nuvectra that Covered Entity is required to include in a Breach notification pursuant to the HIPAA Regulations as the information becomes available to Nuvectra. Covered Entity acknowledges and shall be deemed to have received notice from Business Associate that there are routine occurrences unsuccessful security incidents ("USI"), including: (i) unsuccessful attempts to penetrate computer networks or services maintained by Business Associate; and (ii) immaterial incidents such as "pinging" or "denial of services" attacks. The Parties agree that USI are foreseeable and expected, are not reportable under this paragraph, and that this paragraph provides notice of such USI.

III. OBLIGATION OF COVERED ENTITY

1. Covered Entity shall not request Nuvectra to use or disclose PHI in any manner that would not be permissible under HIPAA, HITECH, the HIPAA Regulations, or any other

applicable federal or state law, if done by Covered Entity or that is not otherwise expressly permitted under this Agreement.

2. Covered Entity shall provide Nuvectra with its Notice of Privacy Practices upon request, as well as any changes to such notice.

3. Covered Entity shall inform Nuvectra of any changes in, or the revocation of, permission by an individual to use or disclosed PHI about the individual, if such changes, or revocation, affect Nuvectra permitted or required uses and disclosures of PHI hereunder.

4. Covered Entity shall notify Nuvectra of any restriction on the use or disclosure of PHI to which Covered Entity has agreed or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect Nuvectra's use or disclosure of Protected Health Information.

5. Covered Entity agrees to mitigate, to the extent practicable, any harmful effect that is known to Covered Entity, of a use or disclosure of Protected Health Information by either Nuvectra or Covered Entity in violation of the requirements of this Agreement.

6. The extent of any disclosures of Protected Health Information made under this Agreement shall be at the sale discretion of the Covered Entity, and Covered Entity warrants that it has the right to make such disclosures to the Business Associate hereunder.

IV. TERM AND TERMINATION

1. Term. This Agreement shall be effective as of the Effective Date and shall continue for as long as Nuvectra is in possession of or able to access Protected Health Information.

2. Termination for Cause. Upon Covered Entity's knowledge of a material breach by Nuvectra, Covered Entity has the right to: (a) provide an opportunity for Nuvectra to cure the breach and terminate this Agreement if Nuvectra does not cure the breach within thirty (30) days after written notice of such violation from Covered Entity; or (b) immediately terminate this Agreement and any agreement(s) between the Parties if Nuvectra has breached a material term of this Agreement and cure is not possible.

3. Effect of Termination.

    a) Except as provided in paragraph (b) of this Section, upon termination of this Agreement for any reason, Nuvectra and its employees, agents and subcontractors shall return or destroy all Protected Health Information and shall retain no copies of the Protected Health Information.

    b) In the event that Nuvectra determines that returning or destroying the PHI is infeasible, Nuvectra shall provide to Covered Entity written notification of the conditions that make return or destruction infeasible. Upon determining that return or destruction of PHI is infeasible, Nuvectra and its employees, agents, and subcontractors shall extend the protections of this Agreement and the HIPAA

Regulations to such Protected Health Information and limit further uses and disclosures of PHI to those purposes that make the return or destruction infeasible, for so long as Nuvectra or its employees, agents, or subcontractors maintain such Protected Health Information.

V. MISCELLANEOUS

1. Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits the Parties to comply with HIPAA, HITECH, and the HIPAA Regulations.

2. No Third-Party Beneficiaries. This Agreement shall not confer any benefit or rights upon any person other than the Parties hereto, and no third party shall be entitled to enforce any obligation, responsibility, or claim of either Party to this Agreement, unless expressly provided otherwise in this Agreement or By Law.

3. Choice of Law. The laws of the State of Texas shall govern this Agreement.

4. Binding Nature and Assignment. This Agreement and the rights and obligations of a Party hereto may be assigned only upon the prior written approval of the other Party. The rights and obligations of the Parties will inure to the benefit of, will be binding upon, and will be enforceable by the Parties and their lawful successors, authorized assigns, and representatives.

5. Notices. Any notices required or permitted under this Agreement shall be deemed effective (a) on the day when personally delivered to a Party, or (b) if sent by registered or certified mail, return receipt requested, on the third (3rd) business day after the day on which mailed, postage prepaid, to such Party at the address listed at the beginning of this Agreement. Either Party may only change its address for notices under this Section by a written notice to the other Party given in accordance with this Section.

6. Waiver. No Waiver or discharge of obligations arising under this Agreement shall be valid unless in writing and executed by the Party against whom such waiver or discharge is sought to be enforced. The waiver by either Party against whom such waiver or discharge is sought to be shall not operate or be construed as a waiver of any subsequent breach of the same or any other provision of this Agreement.

7. Change in Law: Amendments.

    a. A reference in this Agreement to a provision in HIPAA, HITECH, or each of their implementing regulations means such provision as in effect or as amended and all formal guidance issued thereunder.

    b. No amendment or modification to this Agreement will be effective except by a written amendment executed by the Party against whom such amendment or modification is south to be enforced.

    c. The Parties acknowledge that it may be necessary to amend this Agreement from time to time as required by the provisions of the HIPAA Regulations, or

other applicable law, to ensure that this Agreement is consistent with all such laws and regulations. The Parties agree to take such action to amend this Agreement from time to time as is necessary for Covered Entity and Nuvectra to comply with the requirements of the HIPAA Regulations and other applicable laws. The Agreement may be terminated by either Party upon thirty (30) days prior written notice to the other Party, or upon such lesser notice as required by applicable law, if the Parties fail to reach written agreement on modifications to this Agreement needed to comply with the provisions of applicable law.

8. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument. This Agreement may be executed and delivered by facsimile or portable document format (.pdf) transmission.

9. Entire Agreement. This Agreement contains the entire understanding by and between the Parties with respect to the exchange, use, disclosure, and protection of Protected Health Information.

10. Notice. Any notices required or permitted under this Agreement shall be deemed effective (a) on the day when personally delivered to a Party, or (b) if sent by registered or certified mail, return receipt requested, on the third business day after the day on which mailed, postage prepaid, (a) to Nuvectra, at 5830 Granite Parkway, Suite 1100, Plano, Texas, 75024, and (b) if to Covered Entity, at the address set forth on the signature page hereto. Either Party may change its address for notices under this Section by a written notice to the other Party given in accordance with this Section.

[INTENTIONAL PAGE BREAK]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed below by their duly authorized representatives.

Business Associate:

NUVECTRA CORPORATION

By: _____

Name: _____

Title: _____

Covered Entity: (PRINT)

_____

By:* _____

Name: _____

Title: _____

Street 1: _____

Street 2: _____

City/ST/ZIP: _____

The following Covered Entities* are Parties to and covered by this Business Associate Agreement (add additional pages if necessary):

Entity:	Entity:
Street 1:	Street 1:
Street 2:	Street 2:
City/ST/ZIP:	City/ST/ZIP:
Entity:	Entity:
Street 1:	Street 1:
Street 2:	Street 2:
City/ST/ZIP:	City/ST/ZIP:
Entity:	Entity:
Street 1:	Street 1:
Street 2:	Street 2:
City/ST/ZIP:	City/ST/ZIP:

*The signatory for the Covered Entity represents that he or she has the authority to sign on behalf of each and all of the Covered Entities identified above.