Benefit Verification and Pre-Authorization Support Documents

Version: October 2017

Oticon Medical Reimbursement Support Services

Benefit Verification and Pre-Authorization Support Documents

Thank you for choosing Oticon Medical LLC for your hearing solution. Our company is dedicated to bringing the magical world of sound to people at every stage of life. When you choose Oticon Medical, you choose a company made up of people highly experienced and committed to putting patients' needs first. As part of our commitment, we are pleased to offer you Oticon Medical's Reimbursement Support service which has been designed to assist patients who are new to the technology or have previously received the Ponto System or other compatible auditory osseointegrated implants. Our team is responsible for assisting with insurance and reimbursement questions as well as helping to navigate the complexities of benefit verification, pre-authorizations and billing.

In order to assist eligible patients*, we are proving you with the following enclosed documents:

- Reimbursement Support Fax Request
- Pre-Determination and Pre-Authorization Services Checklist
- Reimbursement Support Services Intake Form
- Notice of Privacy Practices
- Patient Acknowledgments and Waivers
- Oticon Medical Billing Service Description
- Patient Bill of Rights and Responsibilities

Additional Items Required for Medicare Patients Only:

- Medicare DMEPOS Supplier Standards
- Medicare Physician Order Form

Please review the documents listed above and refer to the Pre-Determination and Pre-Authorization Services Checklist for a list of items required in order for Oticon Medical's Reimbursement Support Team to assist with your request. Patients may submit requests directly to Oticon Medical, but they will require assistance from their health care provider in order to accurately complete the forms and collect the required clinical documentation.

In order to initiate your request, please submit the required documents to Oticon Medical's Reimbursement Support Team via fax to 732.568.7130. If you are unable to submit these documents via fax, please contact our office and a self-addressed, stamped envelope will be provided to you. Note that all required documents must be on file in our office before we can proceed with processing your request and product order.

Again, thank you for selecting the Ponto System – Oticon Medical's proven bone anchored hearing system. If you have any questions or concerns, please do not hesitate to call Oticon Medical's Reimbursement Support Team at 888.277.8014. We look forward to working with you.

Sincerely,
Oticon Medical LLC

** Please allow a minimum of 4-6 weeks for most insurance pre-authorization requests*

Reimbursement Support Fax Request

FAX

To: Oticon Medical Reimbursement Support Team

From: _____

Fax: 1-732-568-7130

Pages: _____

Phone: _____

Date: _____

Re: _____

CC: _____

The attached request is for:

- ☐ Medicaid: Benefit Check and Pre-Auth for patient's device(s) Clinic will be the billing provider
- ☐ Medicaid: Benefit Check and pre-Auth for patient's device(s) Request for Oticon Medical to be the billing provider
- ☐ Medicare: Benefit Check and Pre-Auth for patient's device(s) Request for Oticon Medical to be the billing provider
- ☐ Surgery Pre-Auth: Benefit Check and Pre-Auth Only for patient's surgery Clinic will be the billing provider
- ☐ Other

The provider is responsible for ensuring that the patient meets all applicable clinical indications as all products should be used according to their labeling. As with all procedures and services, providers should maintain proper documentation. Providers assume full responsibility for all reimbursement decisions or actions. It is always the provider's responsibility to determine and submit appropriate codes and charges for services that are rendered.

Pre-Determination and Pre-Authorization Services Checklist

PLEASE INCLUDE THE FOLLOWING DOCUMENTS WITH ALL REIMBURSEMENT SUPPORT REQUESTS:

Forms:

- ☐ Reimbursement Support Services Intake Form

Releases and Waivers:

- ☐ Notice of Privacy Practices *(Page 4 must be completed and signed by the patient)*
- ☐ Patient Acknowledgements and Waivers *(Completed and signed by the patient)*

Other Required Items:

- ☐ Documentation of Medical Necessity including: Letter of Medical Necessity, Audiogram(s) and other clinical notes/rationale
- ☐ Copy of the Patient's Insurance Card(s) *(Clear/enlarged copies of the front & back)*

Additional Items Required for Medicare Patients Only:

- ☐ Medicare Physician Order Form *(Not required for repair orders)*

*Please note that if additional information or documentation is required in order to process this request, Oticon Medical or the patient's insurance company may contact the health care provider or patient.

Reimbursement Support Services Intake Form

Please return all completed forms and documentation, including a legible copy (front & back) of the patient's insurance card(s), to the Oticon Medical Reimbursement Support Services team via fax to 732.568.7130

PATIENT INFORMATION

Patient Name: _____ Date of Birth: _____ Gender: M ☐ F ☐

Address _____

City/State/Zip: _____

Patient Phone: _____

Patient's Parent/Legal Guardian or Authorized Contact Person: _____

Emergency Contact (Required): _____ Phone: _____

Relationship of Emergency Person: _____

Side(s) Implanted: Right ☐ Left ☐ Date of Original Implant: Right: _____ Left _____

SERVICE REQUESTED

- ☐ Repair Authorization
- ☐ Prior Authorization Request for Surgery
- ☐ Prior Authorization Request for Equipment and Supplies
- ☐ Other: _____

INSURANCE INFORMATION

Primary Insurance:

Insurance Company Name: _____ Insurance Company Phone: _____

Member ID: _____ Group ID: _____

Subscriber Name: _____ Subscriber Date of Birth: _____

Subscriber's Employer: _____

Type of Insurance Plan: HMO ☐ PPO ☐ POS ☐ Medicare ☐ Medicaid ☐ Other ☐

Secondary Insurance:

Insurance Company Name: _____ Insurance Company Phone: _____

Member ID: _____ Group ID: _____

Subscriber Name: _____ Subscriber Date of Birth: _____

Subscriber's Employer: _____

Type of Insurance Plan: HMO ☐ PPO ☐ POS ☐ Medicare ☐ Medicaid ☐ Other ☐

Reimbursement Support Services Intake Form

HEALTH CARE PROVIDER INFORMATION

Required for All Requests

Physician: _____ NPI: _____

Address/City/State/Zip: _____

Phone: _____ Fax: _____

TIN: _____ Medicare PTAN: _____

☐ Contact's Phone: _____ ☐ Contact's Email: _____

Audiologist: _____ Office Contact: _____

Address/City/State/Zip: _____

☐ Contact's Phone: _____ ☐ Contact's Email: _____

EQUIPMENT AND SUPPLIES NEEDED

Not Applicable for Surgical Prior Authorization Requests

Diagnosis: _____ ICD-10 Diagnosis Code(s): _____

☐ L8691: Auditory osseointegrated device, external sound processor, replacement (Ponto Sound Processor)

☐ L8692: Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment

☐ L7510: Repair of prosthetic device, repair or replace minor parts

☐ L8621: Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each

☐ Other: _____

FACILITY INFORMATION

Required for Surgical Prior Authorization Requests Only

Facility Name (where the procedure will be performed): _____

Address/City/State/Zip: _____

Phone: _____ Fax: _____

NPI: _____ TIN: _____

Is Billing Facility in-network with this plan: YES ☐ NO ☐

PROCEDURE

Required for Surgical Prior Authorization Requests Only

Surgery Date, if scheduled: _____ Diagnosis: _____

ICD-10 Diagnosis Code(s): _____

Surgical Codes*: _____ Fax: _____

**Include Applicable CPT Procedure and HCPCS Codes*

Place of Service: Inpatient ☐ Outpatient ☐ ASC ☐ Side to be Implanted: Right ☐ Left ☐ Bilateral ☐

Notice of Privacy Practices

Your Information. Your Rights. Our Responsibilities.

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. **Please review it carefully.**

Your Rights

You have the right to:

- Get a copy of your paper or electronic medical record
- Correct your paper or electronic medical record
- Request confidential communication
- Ask us to limit the information we share
- Get a list of those with whom we've shared your information
- Get a copy of this privacy notice
- Choose someone to act for you
- File a complaint if you believe your privacy rights have been violated

Your Choices

You have some choices in the way that we use and share information as we:

- Tell family and friends about your condition
- Provide disaster relief
- Include you in a hospital directory
- Provide mental health care
- Market our services and sell your information
- Raise funds

Our Uses and Disclosures

We may use and share your information as we:

- Treat you
- Run our organization
- Bill for your services
- Help with public health and safety issues
- Do research
- Comply with the law
- Respond to organ and tissue donation requests
- Work with a medical examiner or funeral director
- Address workers' compensation, law enforcement, and other government requests
- Respond to lawsuits and legal actions

Your Rights

When it comes to your health information, you have certain rights. This section explains your rights and some of our responsibilities to help you.

Get an electronic or paper copy of your medical record.

You can ask to see or get an electronic or paper copy of your medical record and other health information we have about you. Ask us how to do this. We will provide a copy or a summary of your health information, usually within 30 days of your request. We may charge a reasonable, cost-based fee.

Ask us to correct your medical record
You can ask us to correct health information about you that you think is incorrect or incomplete. Ask us how to do this. We may say "no" to your request, but we'll tell you why in writing within 60 days.

Request confidential communications
You can ask us to contact you in a specific way (for example, home or office phone) or to send mail to a different address. We will say "yes" to all reasonable requests.

Ask us to limit what we use or share
You can ask us not to use or share certain health information for treatment, payment, or our operations. We are not required to agree to your request, and we may say "no" if it would affect your care. If you pay for a service or health care item out-of-pocket in full, you can ask us not to share that information for the purpose of payment or our operations with your health insurer. We will say "yes" unless a law requires us to share that information.

Get a list of those with whom we've shared information
You can ask for a list (accounting) of the times we've shared your health information for six years prior to the date you ask, who we shared it with, and why. We will include all the disclosures except for those about treatment, payment, and health care operations, and certain other disclosures (such as any you asked us to make). We'll provide one accounting a year for free but will charge a reasonable, cost-based fee if you ask for another one within 12 months.

Get a copy of this privacy notice
You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically. We will provide you with a paper copy promptly.

Choose someone to act for you
If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices about your health information. We will make sure the person has this authority and can act for you before we take any action.

File a complaint if you feel your rights are violated
If you feel we have violated your rights, you can file a complaint by contacting us via the contact information provided in this document. You can file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to 200 Independence Avenue, S.W., Washington, D.C. 20201, calling 1-877-696-6775, or visiting www.hhs.gov/ocr/privacy/hipaa/complaints/. We will not retaliate against you for filing a complaint. If you have any questions, please contact our Privacy Officer by writing to: Oticon Medical LLC, Privacy Officer, 580 Howard Avenue, Somerset, NJ 08873.

Your Choices

For certain health information, you can tell us your choices about what we share. If you have a clear preference for how we share your information in the situations described below, talk to us. Tell us what you want us to do, and we will follow your instructions.

In these cases, you have both the right and choice to tell us to:

- Share information with your family, close friends, or others involved in your care
- Share information in a disaster relief situation
- Include your information in a hospital directory

If you are not able to tell us your preference, for example if you are unconscious, we may go ahead and share your information if we believe it is in your best interest. We may also share your information when needed to lessen a serious and imminent threat to health or safety.

In these cases we never share your information unless you give us written permission:

- Marketing purposes
- Sale of your information
- Most sharing of psychotherapy notes

In the case of fundraising:

- We may contact you for fundraising efforts, but you can tell us not to contact you again.

Notice of Privacy Practices

Our Uses and Disclosures

How do we typically use or share your health information? We typically use or share your health information in the following ways.

Treat you

We can use your health information and share it with other professionals who are treating you. Example: A doctor treating you for an injury asks another doctor about your overall health condition.

Run our organization

We can use and share your health information to run our practice, improve your care, and contact you when necessary. Example: We use health information about you to manage your treatment and services.

Bill for your services

We can use and share your health information to bill and get payment from health plans or other entities. Example: We give information about you to your health insurance plan so it will pay for your services.

How else can we use or share your health information?

We are allowed or required to share your information in other ways – usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes. For more information see: www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html.

Help with public health and safety issues

We can share health information about you for certain situations such as:

- Preventing disease
- Helping with product recalls
- Reporting adverse reactions to medications
- Reporting suspected abuse, neglect, or domestic violence
- Preventing or reducing a serious threat to anyone's health or safety

Do research

We can use or share your information for health research.

Comply with the law

We will share information about you if state or federal laws require it, including with the Department of Health and Human Services if it wants to see that we're complying with federal privacy law.

Respond to organ and tissue donation requests

We can share health information about you with organ procurement organizations.

Work with a medical examiner or funeral director

We can share health information with a coroner, medical examiner, or funeral director when an individual dies.

Address workers' compensation, law enforcement, and other government requests

We can use or share health information about you:

- For workers' compensation claims
- For law enforcement purposes or with a law enforcement official
- With health oversight agencies for activities authorized by law
- For special government functions such as military, national security, and presidential protective services

Respond to lawsuits and legal actions

We can share health information about you in response to a court or administrative order, or in response to a subpoena.

Notice of Privacy Practices

Our Responsibilities

- We are required by law to maintain the privacy and security of your protected health information.
- We will let you know promptly if a breach occurs that may have compromised the privacy or security of your information.
- We must follow the duties and privacy practices described in this notice and give you a copy of it.
- We will not use or share your information other than as described here unless you tell us we can in writing. If you tell us we can, you may change your mind at any time. Let us know in writing if you change your mind.

For more information see: www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp.html.

Changes to the Terms of this Notice

We can change the terms of this notice, and the changes will apply to all information we have about you. The new notice will be available upon request, in our office, and on our web site.

Other Instructions for Notice

Effective Date of this Notice: February 01, 2017

Please complete this Acknowledgement and return it to Oticon Medical's Reimbursement Department either via fax to 732-568-7130 or by mail to 580 Howard Avenue, Somerset, NJ 08873.

ACKNOWLEDGEMENT

I hereby acknowledge receipt of Oticon Medical's Notice of Privacy Practices.

Patient Name: _____

Signature: _____ Date: _____

If the Patient is a minor child or dependent:
Parent or Legal Guardian Printed Name: _____

Parent or Legal Guardian Signature: _____ Date: _____

Relationship to the Patient: _____

Patient Acknowledgements and Waivers

Assignment of Benefits

For Medicare Beneficiaries:
I understand that Medicare pays for sound processor implants and related surgical services under certain conditions. I understand that Oticon Medical will inform me in advance as to whether it expects Medicare to approve or deny coverage for the services I am seeking given my medical condition and other circumstances. I also understand that I may elect to receive a service from Oticon Medical, even if Oticon Medical believes that coverage by Medicare is unlikely.

If I receive sound processor implants and/or related services from Oticon Medical, by signing this form, I authorize and assign Oticon Medical the right to pursue and receive payment from Medicare, as well as the right to pursue all administrative appeals and litigation, and any other causes of action as necessary to pursue payment. I understand that even if Medicare pays Oticon Medical for the service provided to me, I may be responsible for a deductible, coinsurance, copayment, or other payment amount under the Medicare program rules. I understand that Oticon Medical may bill me for that amount, and I assume responsibility for its payment in full. I also understand that if I receive a service that Medicare does cover under any circumstances, or for which Medicare denies payment because of my medical condition and/or other circumstances, I may be billed by Oticon Medical for the cost of the services rendered to me and I assume responsibility for payment of the billed amount in full. I also understand that if Medicare denies payment for a service I have received, I have the right to appeal that determination.

For All Other Beneficiaries:
I authorize and assign Oticon Medical the right to pursue and receive payment from my insurance carrier, as well as the right to pursue all administrative appeals and litigation, and any other causes of action as necessary to pursue payment related to my receipt of sound processor implants and/or related services from Oticon Medical.

Financial Liability
I understand that if my health insurance does not provide coverage for, or denies payment for, any of the services provided to me, Oticon Medical may bill me for those services, unless doing so would be prohibited by state or federal law, and I assume responsibility for payment of the billed amount in full. I also hereby transfer and assign to Oticon the proceeds of any claim, proceeding, suit and/or action for damages payable to me, my representative or my estate, up to the cost of those services provided to me by Oticon Medical not covered by my health insurance.

I certify that the financial and insurance information I supplied is correct and that I have been informed of my financial obligations.

Use of Information
I understand that my signature on this form gives Oticon Medical the authority to use and/or release my protected health information for treatment, payment and health care operations and as further set forth in the Notice of Privacy Practices.

I have received a copy of patient handouts that include the notice of privacy practices (requires signature), description of services – including how to contact the company and how to file a grievance or complaint, patient bill of rights and responsibilities and Medicare supplier standards.

I certify that I have read these documents/policies and my signature indicates my understanding and consent.

Patient Name: _____

Patient's Signature: _____ Date: _____

If the Patient is a minor child or dependent:
Parent or Legal Guardian Name: _____

Parent or Legal Guardian Signature: _____

Relationship to the Patient: _____ Date: _____

Billing Service
A Description of Services

Oticon Medical's reimbursement support services, including the billing service, are designed to serve patients who have received the Ponto System or other compatible auditory osseointegrated hearing implants. The billing service is responsible for assisting patients with their orders and with the complexities of coverage, billing and payment for parts and services by Medicare, Medicaid and private insurance plans. The service facilitates patient access to parts and services needed to keep their implantable hearing device in working order. Parts and services may include items such as new or replacement sound processors or repairs required to maintain function of the patient's implant system.

The billing service is not designed to assume insurance or financial responsibility for all costs associated with a patient's auditory osseointegrated hearing implant, nor can it assume responsibility for the coverage limitations of any federal, state or private insurance health plan. As a contracted Medicare provider, Oticon Medical's billing service is designed to primarily support Medicare patients.

Patients eligible to participate in Oticon Medical's billing service program must:

1) Have been implanted with an Oticon Medical Ponto System;
2) Have been implanted with a compatible version of other auditory osseointegrated hearing implants;
3) Be currently covered, or covered at the time the part or service was provided, by Medicare or a payer that Oticon Medical is able to bill for parts and services;
4) Be a resident of the United States or US Territories.

Working with private insurance plans and government health plans requires cooperation among the patient, the treating clinician, and Oticon Medical's reimbursement support team:

Patient: Patients must understand their benefits. Oticon Medical will help navigate these programs, and their limitations, as they apply to specific patient need; however, patients should be familiar with the fundamental concepts of these insurance programs' coverage for the external parts and repairs associated with their implantable hearing device. Patients should work with their professional health care provider to document medical necessity, and follow payer and Oticon Medical referral procedures. For Medicare beneficiaries and other patients, at the time of purchase patients should be prepared to pay Oticon Medical their out-of-pocket responsibility associated with the part or service provided.

Additionally, Oticon Medical is not contracted with all Medicare or Medicaid programs or private insurance plans or the patient may find that their plan does not provide coverage for the requested parts or services. Patients may be directed to their provider or other providers who may be contracted with those programs.

Clinician: The treating clinician must establish and document the medical necessity of the part or service needed by the patient. This may require the completion of a Physician's Order, Letter of Medical Necessity or other supporting documentation. They must also comply with the payer and Oticon Medical's referral processes.

Oticon Medical: Oticon Medical will comply with all payer coverage and billing guidelines, and will submit a claim in a timely fashion. Oticon Medical will also work with the patient, the clinician and the payer to facilitate coordination of benefit (COB), Medicare as Second Payer (MSP), and Medicaid "payer of last resort" requirements based upon individual patient situations. Oticon Medical's reimbursement support team welcomes constructive comments regarding our products and services. Please contact the company directly regarding complaints and grievances by calling the following toll free number 888-277-8014. Oticon Medical will handle calls in a responsive manner and in compliance with accreditation standards. Additionally, patients may file a complaint or grievance regarding Oticon Medical's complaint handling policy and procedures with the following:

- The Accreditation Commission for Health Care at 919-785-1214; or
- Medicare at 800-633-4227 or TTY users may call 877-486-2048; or
- New Jersey Dept of Consumer Affairs at 973-504-6200.

Billing Service

When a part or service is needed, the patient or their clinician may contact Oticon Medical's reimbursement support team by mail, fax, telephone or e-mail. A member of Oticon Medical's reimbursement support team will obtain the required information in order to process the order and will begin the process by verifying the patient's current health insurance status and eligibility to participate in Oticon Medical's billing service. Upon receipt of all necessary information, successful verification of coverage and benefits and the timely completion of any required pre-authorization requirements, Oticon Medical will ship the product or, if on backorder, will provide a shipping date. Once the product has been shipped, Oticon Medical will submit a claim to the applicable payer(s).

If Oticon Medical's reimbursement support team can provide you with any additional information or answer any questions regarding our services or to request an Oticon Medical product catalog and/or pricing, please contact Oticon Medical at:

Oticon Medical, LLC
580 Howard Ave
Somerset, NJ 08873
888-277-8014 (toll free)
732-868-6949 (fax)
E-mail at info@oticonmedicalusa.com

Hours of Operation:
Monday – Friday
8am – 7pm Eastern Standard Time

Patient Bill of Rights and Responsibilities

Billing Service
Patient Bill of Rights and Responsibilities

Courtesy, dignity, confidentiality, communication and privacy are essential to Oticon Medical's billing services. Oticon Medical will strive to ensure all employees regard and uphold these rights. Patients have the right to:

1. Be fully informed in advance about the part, accessory or service to be provided and any modifications to the plan of care that may occur.
2. Be informed both orally and in writing of the charges, including payment expected by third parties and any charges for which the patient will be responsible.
3. Be fully informed of patient responsibilities regarding billing Medicare and Medicaid (and, in some cases, commercial health plans) for medically necessary parts and repairs.
4. Be informed of Oticon Medical's Billing Service scope of service and limitations on those services.
5. Participate in the development and periodic revision of their plan of care.
6. Refuse care or treatment after the consequences of refusing care or treatment are fully presented.
7. Have one's property and person treated with respect, consideration, dignity and with recognition of the patient's individuality
8. Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property.
9. Voice grievances/complaints regarding treatment or care or lack of respect of property, or recommended changes in policy, personnel, or services without restraint, interference, coercion, discrimination or reprisal.
10. Have grievances/complaints investigated and resolved in a timely and appropriate manner.
11. Confidentiality and privacy of all information contained in the patient's record and of Protected Health Information (PHI). The patient also has the right to receive a copy of Oticon Medical's Notice of Privacy Practices describing ways in which the company may use and disclose patient PHI and to be advised on Oticon Medical's policies and procedures regarding disclosure of clinical records.
12. To choose their own health care provider. Oticon Medical provides access to parts, accessories and services required to maintain function of their implantable hearing device.
13. Receive service, parts, accessories and repairs without discrimination as to race, color, religion, sex, age, national origin, disability or sexual orientation in accordance with the physician's orders, if applicable.
14. Be informed of any financial benefits Oticon Medical may receive when referring the patient to another company.
15. Be represented by a parent, guardian, family member or other representative if the patient is unable to fully participate in his or her decisions or requires that they speak on their behalf.

Patients with the Ponto System, or other compatible osseointegrated implantable hearing devices, who need external parts, accessories and repairs are expected to provide all information requested by Billing Service personnel necessary to complete a billing transaction. Recipients are expected to:

1. Present complaints concerning products or services.
2. Respect the rights of others including Oticon Medical personnel.
3. Report when they lack a clear understanding of Medicare, Medicaid or commercial health plan benefits covering needed parts and services, and what may be expected of them.
4. To have necessary Medicare, Medicaid or commercial health plan benefit billing information available at the time of the order.
5. Become familiar with their Medicare, Medicaid or commercial health plan benefits and coverage policy concerning external parts and repairs for implantable hearing devices.
6. Assure that the financial obligations associated with the purchase of parts and repairs, including co-payments and fees for non-covered services, are met in a timely manner.
7. To use their health plan benefits in an honest manner.
8. Work with their professional caregiver to ensure adherence with federal, state and Oticon Medical referral procedures, and receipt of proper and necessary authorization for parts and repairs needed.
9. Respect loaner sound processors, or other Oticon Medical property, and return loaned products in a timely manner and in good working condition.
10. Inform the Billing Service, in a timely manner, in the event of changes to name, address or health insurance status.

Medicare Supplier Standards

Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57 (c) (11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair cost either directly, or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services (except for certain exempt pharmaceuticals).
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57 (d).
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics.

Medicare Physician Order Form

SECTION A

Certification Type/Date: Initial _____/_____/_____ Revised _____/_____/_____ Recertification _____/_____/_____

Patient Name, Address, Telephone # and HIC #:

(_____) _____-_____ HIC# _____

Patient Date of Birth _____/_____/_____

Supplier Name, Address, Telephone # and NCS/NPI #:
Oticon Medical LLC
580 Howard Ave
Somerset, NJ 08873
888) 277-8014

NSC/NPI# _____

Sex: _____ (M/F)

Physician Name, Address, Telephone # and NPI/UPIN:

(_____) _____-_____ NPI/UPIN# _____ Place of Service: _____

SECTION B *This section may not be completed by Oticon Medical LLC.*

Date of Physician's Examination: _____/_____/_____

Estimated Length of Need (# of months): _____ 1-99 (99 = Lifetime)

Diagnosis Codes (ICD-9): _____ _____ _____

SECTION C *Narrative Description of Device and Cost*

1) Narrative description of items ordered: Auditory osseointegrated device, Ponto System external sound processor, replacement. HCPCS code: _____

2) Oticon Medical charge: $ _____

3) Medicare DMEPOS Fee Schedule: $ _____

SECTION D *Physician Attestation and Signature/Date*

I certify that I am the treating physician identified in Section A of this document. I have received Sections A, B and C of this document including the charges for items ordered. Any statement on my letterhead attached hereto has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

Physician's Signature _____ Date _____