Reimbursement Process and Procedure Guide

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Reimbursement Process and Procedure Guide

It is important that you understand the reimbursement process and procedures that affect our products. It is equally as important that you are able to provide your physicians and their staff with the appropriate reimbursement information/resources in the appropriate setting or circumstance given Cephalon policies and procedures. This Reimbursement Process and Procedure Guide provides the necessary information and related resources to assist you in navigating through the reimbursement process.

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Reimbursement Support
(As of July 1, 2008)

Please refer to Section 7: Reimbursement Support in the US Sales and Marketing Policy Handbook.

Reimbursement Discussions

Sales representatives may proactively discuss on-label reimbursement issues with healthcare professionals and other staff who are involved with reimbursement issues. Any such discussion must be based on either PDRC approved pieces or on-label reimbursement information that is provided by National Account Managers (NAMs) or Cephalon Reimbursement Managers (CRMs). In addition, sales representatives may only distribute reimbursement material that has been either approved for that purpose by PDRC or provided by NAMs or CRMs to the sales representative. If a healthcare professional or other staff requests additional reimbursement coverage information, the sales representative should either refer the healthcare professional to the Cephalon Reimbursement Hotline, provide contact information to enable the healthcare professional to directly contact the third party payor and/or offer the assistance of a NAM or CRM.

The following are examples that are included here in order to provide guidance as to what is and is not acceptable in terms of both discussions and questions.

- "Doctor, XYZ Plan has added PROVIGIL to the second tier of its three tier formulary for ES associated with OSA which means your patients will pay a formulary co pay and you will not be required to go through a PA process"...**Acceptable**
- "Doctor, did you know that XYZ plan covers PROVIGIL as adjunct therapy for depression"...**Unacceptable**
- "Doctor, have you had trouble getting reimbursed for using FENTORA for back pain"...**Unacceptable**
- "Doctor, you mentioned you are having some issues in getting PROVIGIL covered for patients with ES associated with OSA. Which plans are giving you the most trouble?"...**Acceptable**
- "Doctor, I would like to take a moment and discuss a reimbursement issue with PROVIGIL which is discussed in this core visual aid. As you can see it points out that...**Acceptable**

Reimbursement Support-continued

Diagnosis Code Information and ICD-9 Codes
It is only appropriate to discuss ICD-9 codes for on-label indications with a healthcare professional when the specific codes are included in PDRC-approved promotional materials. Healthcare professionals with questions about coding should be referred to their own ICD-9 book or to the Cephalon Reimbursement Hotline for the applicable product. It is never appropriate for a sales representative to suggest a code, diagnosis or a reimbursement strategy to a healthcare professional.

The following are examples that are included here in order to provide guidance as to what is and is not acceptable in terms of both discussions and questions.

- *Sales Specialist* – "Doctor, XYZ plan may not cover PROVIGIL for Parkinson's, but if you code idiopathic hypersomnia, it is usually covered." **Unacceptable**
- *Sales Specialist* – "Doctor, try code _____ for your FENTORA patients." **Unacceptable**
- *Doctor*- "I am having trouble getting PROVIGIL coverage for my MS patients"
  Sales Specialist -"Have you tried coding for Parkinson's instead? That seems to work for XYZ plan in this area." ...**Unacceptable**
- *Sales Specialist* – "As you know, PROVIGIL is indicated for _____. For reimbursement assistance you may call the Reimbursement Hotline." **Acceptable**
- *Sales Specialist* – "Doctor, FENTORA is indicated for opioid tolerant patients with BTCP. For reimbursement assistance you can either contact the Reimbursement Hotline or the health plan." ...**Acceptable**
- *Sales Specialist* – "Doctor, health plans often require a prior authorization for the approval of many drugs. If you include information about poor response to other short acting opioids and state that the onset of action is much faster for FENTORA, you'll have a better chance of getting FENTORA covered."...**Unacceptable**
- *Doctor* – "What is the ICD-9 code for SWSD"?*Sales Specialist* – "Doctor, to obtain the appropriate code for SWSD, I would recommend you contact the Reimbursement Hotline or refer to your ICD-9 code book."...**Acceptable**

NOTE: If the ICD-9 code for SWSD is included on a PDRC approved promotional piece, the Sales Specialist may provide the code to the HCP.

Reimbursement Support-continued

Reimbursement Documentation

In response to a specific unsolicited question or comment from a healthcare professional about a denied claim, the sales representative may obtain the reimbursement form, such as a letter or denied prior authorization, from the healthcare professional, as long as such material is HIPAA-compliant. HIPAA-compliant means that all patient identifiable information must be omitted or blocked by the office prior to the sales representative seeing the document. The sales representative may not discuss the claim denial with the healthcare professional and must forward the HIPAA-compliant material to a NAM or CRM.

If the NAM or CRM identifies an administrative error that was made by the HCP, the National Account manager may contact the healthcare professional and point out the administrative error. The NAM or CRM may also discuss the general components of the prior authorization, appeal and external review process; however, he/she may never discuss any coding or reimbursement issues/strategies with the healthcare professional. The NAM or CRM may also contact the Plan if he/she believes that the Plan is not following its own policy.

The following are examples that are included here in order to provide guidance as to what is and is not acceptable in terms of both discussions and questions.

- *Doctor*- "When I asked you if the state Medicaid program covered PROVIGIL for OSA you said yes. I just received a denial. Can you help me?"
  Sales Specialist - "You have several options, you can contact the state Medicaid plan directly, you can contact the Cephalon reimbursement hotline for support or if there is any specific HIPAA compliant documentation that you can provide, I can pass it along to one of my National Account Managers who may be able to provide further guidance." ...**Acceptable**

- *Doctor* – "I just had another patient denied by plan xyz. Unless these plans start covering PROVIGIL for depression, I am going to stop prescribing PROVIGIL. Can you help me?"
  Sales Specialist – "Doctor, PROVIGIL is indicated for excessive sleepiness associated with narcolepsy, SWSD and as an adjunct to CPAP for OSA. If there is any specific HIPAA compliant documentation that you can provide, my National Account Manager should be able to get it covered for you by contacting the plan directly." ...**Unacceptable**

Reimbursement Support-continued

- *Doctor* – "XYZ Plan has covered my MS patients before. I've just received several denials. Has the coverage policy changed?"
  Sales Specialist – "Doctor, PROVIGIL is indicated for excessive sleepiness associated with narcolepsy, SWSD and as an adjunct to CPAP for OSA. In connection with your question, may I suggest that you contact the Cephalon reimbursement hotline for support or if there is any specific HIPAA compliant documentation that you can provide, I can pass it along to one of my National Account Managers who may be able to provide further guidance." ...**Acceptable**

Summary
It is critical that, as a Sales Specialist, you understand reimbursement issues as well as the scope in which you can address questions.

There are two types of reimbursement discussions:
- An unsolicited request for specific reimbursement information which is initiated by the HCP.
- A proactive discussion which is initiated by the Sales Specialist.

Do:
- Proactively discuss on-label reimbursement issues with HCPs that is included in either (i) PDRC approved pieces or (ii) on-label reimbursement information provided by National Account Managers to the Sales Specialist.
- In response to an unsolicited request by HCP:
  - State the approved indication for the product if the question involves an off-label issue
  - Provide payer contact information to allow the HCP to contact the third party payer.
  - Provide information about the Cephalon reimbursement Hotline.
  - Offer to bring in a National Account Manager.

Don't
- Pro-actively initiate discussion around reimbursement issues that would promote or suggest off label use of Cephalon products.
- Show, discuss, or distribute to any customer ICD-9 code tables except for those codes provided in approved PDRC sales pieces.
- Show or distribute the NAM Formulary Grid Sheets.
- Suggest or coach reimbursement strategy to gain approval from a 3rd Party Payer.

Prior Authorization Process

Consistent with Cephalon's Reimbursement Policy, a Sales Specialist may provide the following general information to a HCP about the prior authorization process. However the Sales Specialist may not in any way discuss any off-label indications in connection with such discussion.

Managed Care Organizations (MCOs) are requiring health care professionals to complete Prior Authorization Forms for pharmaceutical products and medical procedures with greater frequency.

It is important to remember that if a MCO requires that a health care professional complete a Prior Authorization Form, it does not mean there is no access for that product.

Understanding and explaining the Prior Authorization Process to health care professionals is an important step in ensuring that their patients can secure access to Cephalon products.

<u>Prior Authorization (PA) Process-Overview</u>

- Physician prescribes medication
- Patient brings prescription to pharmacy
- Pharmacist enters pertinent drug information into the computer
- Pharmacist receives denial from insurance company to fill prescription
- Pharmacist informs patient and calls physician's office
- The physician can either
  - Allow pharmacist to switch to a formulary medication

    OR
  - Inform pharmacist that he/she will request approval from the insurance company

At that point:

- Physician fills out a PA Form or calls the insurance company to get approval
- Insurance company approves or denies the medication
- If denied, the physician and the patient have the right to appeal

Note: Remember, you cannot provide direction concerning the completion of a Prior Authorization Form.

Prior Authorization Process-continued

Expediting the Prior Authorization Process

If the physician or office staff knows the plan routinely requires a Prior Authorization for the medication, a Prior Authorization can be generated at the time the prescription is written.

- In general the physician, nurse, or office manager calls the insurance company or faxes the following information that is usually required on a PA form provided by the insurance company:
  - Physician's name, specialty, address, and phone and fax numbers
  - Member's name, ID#, date of birth
  - Patient's diagnosis
  - Name of specific medication(s) tried and failed
  - Reason for medication request
  - Patient's pertinent medical test results

- Additional information that may be included on the PA form:
  - Reason why "preferred" drugs may be contraindicated (if appropriate)
  - Positive response to product samples

In addition to the general information discussed above, the Sales Specialist can provide the following information to the appropriate office personnel to help with the process.

- The Reimbursement Program brochure. This brochure is an overview of the services available to assist in the Prior Authorization Process. Additional information about the brochures are included in Appendices A and B.
- A specific Managed Care Organizations website for the physician to request or download a Prior Authorization Form.
- Reimbursement Hotline/Consent to Release Medical Information Tear Pads (see Appendices A and B)
- Blank Prior Authorization Forms can be provided upon unsolicited request from the HCP. These forms can be obtained from your National Account Manager or from the specific managed care website.

Note: Remember, you cannot provide direction concerning the completion of a Prior Authorization Form.

Prior Authorization Questions

- Why would a plan require that a Prior Authorization Form be completed for some drugs?

  Many plans require that a Prior Authorization Form be completed to ensure appropriate use of the drug; control the use of high cost drugs; or because a PA form is required due to contractual agreements with other manufacturers.

- What if the health care provider complains that he/she is continuously denied access for our products within a Managed Care Organization (MCO)?

  Putting the physician's concerns into perspective is essential when addressing this issue. Many physicians only remember their negative contacts with an MCO and a product. If a health care professional prescribes a product for 30 patients and three are denied by the MCO, it is the three denials that leave the lasting impression. Pre-call planning and knowing the MCOs that influence their practice may help in defusing this situation. It may also be helpful to contact your National Account Manager (NAM) for more assistance.

  Information on specific MCO reimbursement for Cephalon products can be found on the Formulary Grid Sheets provided by your NAM. More information about the Formulary Grid Sheets is provided in a separate portion of this guide. Keep in mind that these Formulary Grid Sheets are for your educational purposes only and are not to be used as promotional pieces.

Note: Remember, you cannot provide direction concerning the completion of a Prior Authorization Form.

Prior Authorization Appeal Process

Appeal Process

- What is the appeal process?

The appeal process occurs when an initial Prior Authorization request is denied. It requires the submission of additional information offering additional medical justification (i.e., Letter of Medical Necessity [LMN]) to have a non-formulary medication, or a medication in which the plan's criteria for coverage is not met, approved for coverage. Note: Letters of Medical Necessity will be explained in greater detail in the LMN section.

There are two types of appeals: Internal and External. The internal appeal is the first step in the process if a Prior Authorization is denied. The physician may have more than one internal appeal opportunity based on the specific managed care plan's policy. In general, the internal appeal is physician-driven and the external appeal is patient-driven and can be submitted when the internal review options have been exhausted. However this may vary by state.

Internal Appeal Process

- For the internal appeal process the physicians must do the following:
  - Read the denial letter carefully. Most letters will provide information on reasons for denial and steps to appeal the decision made by the insurance company.
  - Submit a copy of the denial with additional medical justification, a LMN, or call the insurance company for verbal discussion and approval.
    - (**Note:** LMN will be explained in the LMN section later in the guide.)
  - Provide the insurance company with appropriate appeal form(s) or a letter containing the following information:
    - Patient's name, insurance plan, ID # or group #
    - Copy of patient's chart with appropriate diagnosis and test results
    - List of medications tried and failed (including any OTC medications)
    - Reason for failure and
    - Medical justification for prescribing medication in question.
  - Send all pertinent appeal information directly to the person who signed the denial letter or to the address indicated in the denial letter.

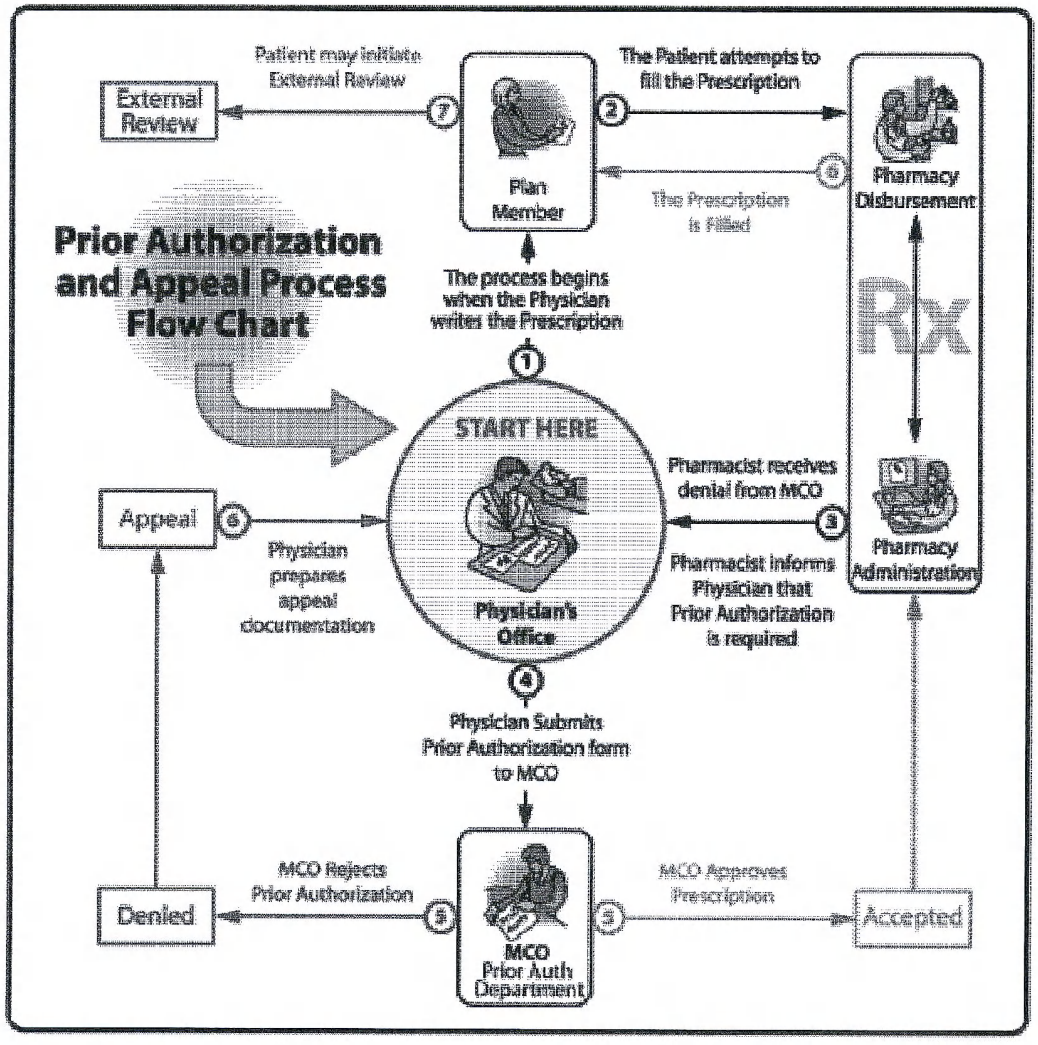
Facilitating the Appeal Process

Physicians may utilize Cephalon's Reimbursement Hotlines for assistance with the appeal process. Additional information pertaining to the Reimbursement Hotlines can be located in this Reimbursement Process and Procedure Guide in the Reimbursement Assistance Information section.

See the illustration of the process flow on the following page.

Note: Sales Specialists can only provide the HCP with this general information about the appeal process and Reimbursement Hotline information. Sales Specialists cannot participate in the appeal process.

Illustration of the Process Flow
A Typical Internal Appeal Process



Note: Appeals process and levels may vary depending upon specific insurance company, plan, and state requirements.

Illustration of the Process Flow
A Typical Internal Appeal Process

External Review Process

External Review Process

An external review is a process initiated by the patient when they disagree with a decision made by their managed care plan that has excluded them from a health benefit. On occasion, the physician can initiate this process if authorized by the patient. The external review board typically is handled by a state-governed agency. The board is comprised of independent physicians who have no relationship with the managed care plan that is involved with the specific case. An external review case is estimated to cost the managed care plan in the range of $1,000–$2,000 per case. In most states, the patient incurs no cost for this process. The patient's physician will often be asked to submit pertinent documentation relative to the case.

Again, if the prior authorization and internal appeal processes result in denial of access to Cephalon products, many states allow **patients** to request an external review from a state-governed external review board. This process often is documented in the communication from the managed care plan when they send the denied appeal documentation. The process typically is outlined very explicitly

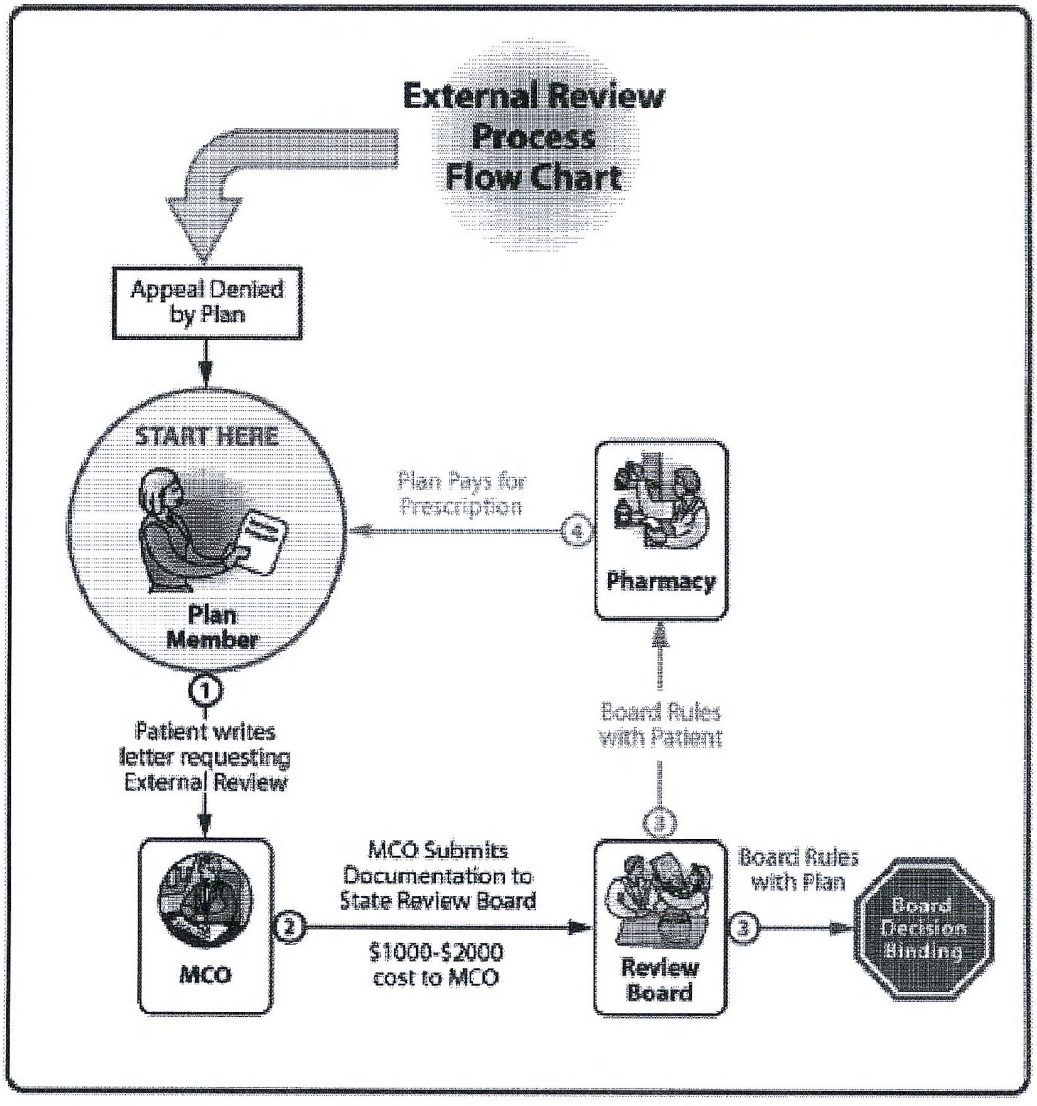
Below is an example of the process.

- Patient and physician receive denied appeal documentation from the managed care plan.
- Patient writes a letter to the managed care plan, requesting an external review.
- Managed care plan sends all documentation for the case to the external review board.
- Independent physicians review the case and submit their findings (which are binding). If the external review process favors the patient, the plan must pay for the prescription medication.

See the illustration of the process flow on the following page.

Note: Sales Specialists can provide HCPs with this general information regarding the External Appeal Process and Reimbursement Hotline information. Sales Specialists cannot participate in the review process.

Illustration of the Process Flow
A Typical External Appeal Process



Note: Appeals process and levels may vary depending upon specific insurance company, plan, and state requirements

Letters of Medical Necessity

Letters of Medical Necessity

Letters of Medical Necessity (LMN) are a key component in the successful completion of the appeal process. Typically utilized after an initial prior authorization is declined, health plans may request that a physician provide additional supporting documentation in the form of a "patient appeal" or letter that includes a more detailed patient history.

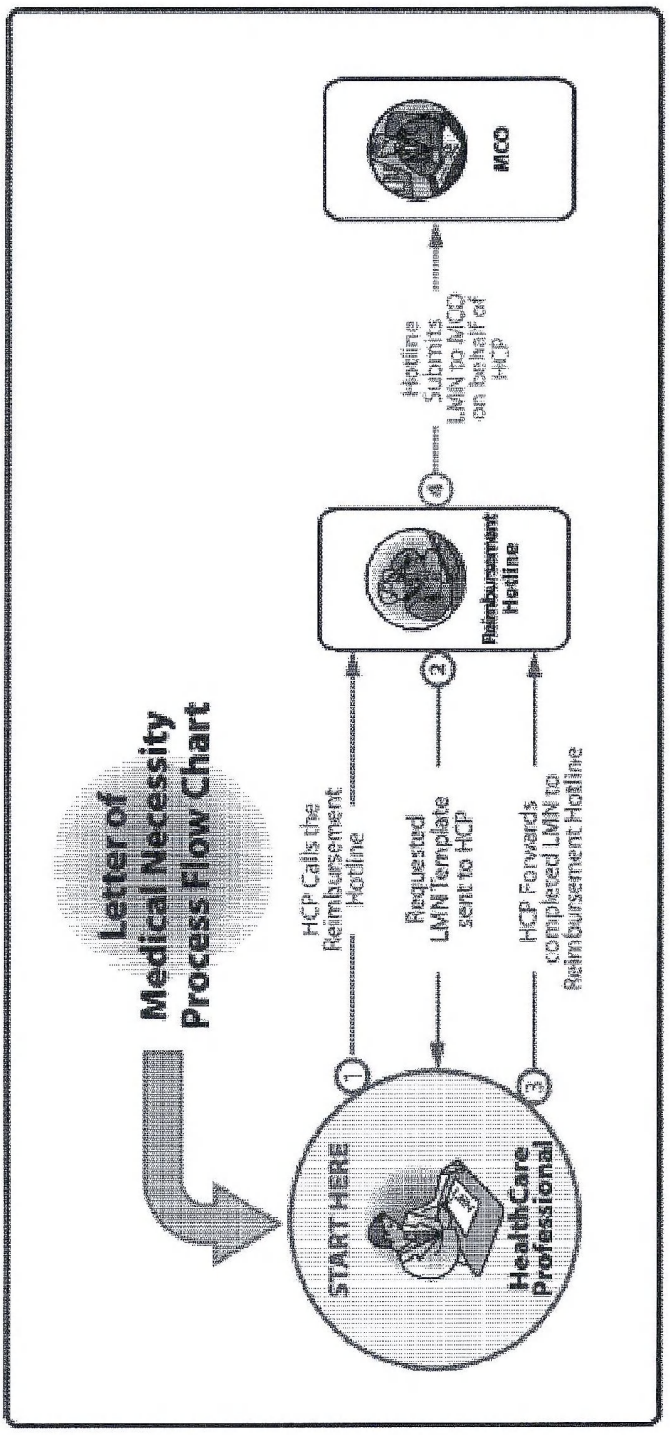
Sales Specialists may proactively make the HCP and/or office staff who is involved with reimbursement, aware of Cephalon's hotline support programs to help with reimbursement issues which could include support with LMN's.

To receive a template Letter of Medical Necessity, the physician/office must contact the Reimbursement Hotline and state the specific clinical area/indication for which they are interested in receiving a LMN.

Sales Specialists may also forward the HCP's unsolicited request for a LMN to Cephalon's Medical Services department through the Cephalon's "MIRF" (Medical Information Request Form) process. However, the most expedient way for the HCP to access the LMN is directly through the Reimbursement Hotline service.

The Letters of Medical Necessity can be provided to the physician electronically in an email or they can be provided to the physician on a CD-ROM. The physician can choose either format. The LMN will be sent to the physician in the requested format .

Letters of Medical Necessity Process Flow



Reimbursement Assistance Information

Cephalon has developed a Reimbursement Hotline to provide assistance to your customers. This resource provides reimbursement assistance and supports our patient assistance programs for patients who may not have insurance coverage and do not have the financial means to pay for our products. As with any resource, *it is your responsibility to understand how to appropriately utilize and position the reimbursement hotline with your customers.* Successfully communicating realistic expectations of the Reimbursement Hotlines' role and capabilities will continue to generate satisfied customers. While these services are in place to facilitate the reimbursement process and ease the administrative burdens of the process, **these services do not replace the HCP's clinical role or responsibility to submit accurate coding and billing information that meets third-party payer coverage and reimbursement requirements.** The physician and their staff have a continuing role as described later in this section.

Information regarding the Reimbursement Hotline brochures are available in Appendices A and B and can be ordered through Promotech.

The Reimbursement Hotline provides customers with basic reimbursement assistance including template letters of medical necessity and answering general coding and coverage questions.

The Reimbursement Hotlines also provide patient specific benefit research, prior authorization and prior authorization appeal research and assistance. On behalf of a health care provider, the Hotline Program staff:

- provide guidance regarding prior authorization and appeals processes;
- research the payer's specific requirements for prior authorization or appeals;
- inform HCPs about the need to submit prior authorization and appeal forms to the provider;
- provide template Letters of Medical Necessity;
- submit completed prior authorization documentation to the payer;
- stay on hold with payers to get status updates; and
- follow up with the insurance companies until a decision is rendered.

Reimbursement Assistance Information-continued

The health care provider's role includes:

- crafting Letters of Medical Necessity (using templates or separately),
- completing prior authorization forms, and,
- gaining written consent from the patient before sharing any personal information with the Reimbursement Hotline (see Appendices A and B).
- meeting payer coverage and reimbursement policy requirements (i.e., furnish the necessary codes and supporting billing information).

The Reimbursement Hotline also can help patients access the Patient Assistance Programs. This is discussed in more detail in the Patient Assistance Program section of this guide.

Finally, the Reimbursement Hotline can provide response to unsolicited requests from physicians' offices regarding payer policies, regardless of indication, using publicly available payer policy information. This information will be provided verbally during hotline's initial conversation with health care personnel. In no way is this service designed to advocate, imply, direct, or recommend any specific use of a Cephalon product.

- The Hotline will set expectations with callers that the information being provided to them is **general coverage information** for the payer and that requirements may vary for the patient's specific plan.
- The Hotline will not solicit or permit the HCP to provide patient protected health information (PHI) when providing general payer coverage information to health care providers. If the health care provider requests patient-specific research, patient written consent will be required.

Please see Appendix C: General Payer Policy Information Process Flowchart

Reimbursement Hotline Questions

What is the Reimbursement Hotline?

Cephalon offers toll-free Reimbursement Hotlines to provide information and answer questions about reimbursement, assist with prior authorizations and appeals, and support patient assistance programs. See Appendices A and B for product specific information.

What can the Reimbursement Hotline do for my customers after a consent form is signed by the patient?

- Verify prescription coverage under private insurance/managed care, Medicaid, or Medicare Part D plans
- Assist in identifying coverage options for patients
- Provide template letters of medical necessity via e-mail or CD-ROM for customization by the physician
- Provide general guidance for filling out the necessary forms and letters to obtain prior authorization
- Help support the appeal of denied authorization requests or claims
- Follow up with payers to determine the outcome of prior authorization requests or appeals
- Call insurers and stay on the line until the insurer provides an answer

What can't the Reimbursement Hotline do for my customers?

- Work on cases without patient consent
- Obtain prior authorizations and overturn appeals without physician involvement in completing forms and providing clinical documentation
- "Cold call" patients or physicians to offer reimbursement information or assistance
- Speed insurer processing time
- Negotiate or renegotiate payer contracts
- Relay results of insurer research in writing
- Affect or attempt to affect clinical decision-making
- Pre-fill or in any way complete template letters of medical necessity or prior authorization forms

Reimbursement Hotline Questions-continued

What can I do to expedite service by the Reimbursement Hotline and set appropriate expectations with my customers?

- Have the provider fax in a completed request/consent form (See Appendices A and B)
- Remind the provider that they need to submit a signed request/patient consent form in order for the hotline to provide assistance on the case (See Appendices A and B)
- Ask the provider to fax in any relevant denial letters or explanation of benefits (EOB)
- Remind the provider that they will need to sign and submit insurer forms

What should I do for my customers who want to know if a patient qualifies for the Patient Assistance Program?

- Have the customer call the appropriate Reimbursement Hotline to see if the patient qualifies. (See Appendices A and B)

Program representatives are available Monday through Friday, 9:00 a.m. to 8:00 p.m. Eastern Time. During non-business hours, callers may leave messages in a dedicated voicemail box. Voicemail messages are returned within one business day.

Reimbursement Hotline for Sales Specialist Questions

Call 866/495-0656 for Assistance

Cephalon offers a dedicated Sales Force Hotline for FENTORA™ and PROVIGIL® reimbursement issues. Reimbursement hotline representatives are available to address any questions or concerns that field representatives have about the FENTORA™ Reimbursement Program and Patient Assistance Program and the PROVIGIL® Reimbursement Hotline.

The Sales Force Hotline is available from 9:00 am to 8:00 pm EST, Monday through Friday. If the inquiry is related to a specific customer, please provide the following information to speed the request:

1. Prescriber's first name
2. Prescriber's last name
3. Office telephone number
4. Office contact name
5. Approximate date of submission

Please remember not to provide or mention any patient-identifiable information, and realize that the Sales Force Hotline will not be able to provide any patient-identifiable information in return.

The goal is to return all calls and inquiries within one business day. However, some research may take two to three business days to complete, depending on current call volume. If the research requires more than three business days, you will receive an update alerting you on the progress.

The Sales Force Hotline gives Cephalon field representatives direct access to Reimbursement Hotline staff to address questions without impacting the HCPs ability to reach the main hotlines.

Call 866/495-0656 for Assistance

Note: The Sales Force Hotline number is intended only for the field force and is not to be disseminated to customers. Your physicians, patients and other customers should call the official product Reimbursement programs. See Appendices A and B for specific program details.

Patient Assistance Programs

Patient Assistance Programs are available to assist patients who do not have any other coverage options and who meet eligibility criteria. Eligibility is based on insurance status, income, and residency/citizenship status. Refer customers who inquire about the Patient Assistance Programs to the appropriate Reimbursement Hotline. (See Appendices A and B for FENTORA and PROVIGIL Patient Assistance Programs).

Program staff will pre-screen the patient and send an application to those who are likely to qualify. Upon return of the application and required documentation, the Patient Assistance Program will determine whether the patient is eligible. If the patient is eligible, they will be enrolled for 12 months, at which point the patient will need to be re-screened and, if still eligible, re-enrolled.

Formulary Grid Sheets

Formulary Grid Sheets Questions

What are Formulary Grid Sheets?

- The Formulary Grid Sheets are a guide to help you understand how different Managed Care Organizations (MCO), Medicaid, and Pharmacy Benefit Managers (PBMs) will cover Cephalon Products.
- The Formulary Grids are updated by the National Account Manager and distributed on a quarterly basis.
- The most important items on this grid sheet are plan:
  - Formulary coverage of Cephalon Products
  - Pharmacy Benefit Structure
  - Prior Authorization Guidelines and Comments
  - Average co-pays

The grid sheets provide the approximate number of lives enrolled in specific plans.

The grid sheet will break down the MCO and PBM into their different benefit designs, (i.e. two tier versus three tier) and illustrate the coverage status for Cephalon products. State Medicaid demographics and coverage information is also included in the Formulary Grid Sheets.

What can I do with the Formulary Grid Sheets?

- Review the grid sheets to understand how your products are reimbursed by Managed Care plans. If the grid sheet states that, in connection with on-label indications, your product is on formulary for 90% of the lives and requires a Prior Authorization for the other 10%, use that information to educate your physicians that 1 out of 10 patients for that specific managed care plan may need the physician to complete a prior authorization.
- At the bottom of the spreadsheet are tabs with the different National Account Manager's names that represent their specific geographies. Look for the NAM that has responsibility for your geography to find updates on the plans that impact your business.

Note: Formulary Grid Sheets are for your educational purposes only and are not to be used as promotional pieces or shown to your healthcare providers. An example of the Formulary Grid Sheet is included at the end of this section.

Formulary Grid Sheets Questions-continued

What is the difference between a National Plan and Regional Plan?

- Regional plans typically cover lives within a specific geography like the state of California. National Plans will usually cover patient lives throughout most of the United States. The designation of Regional or National plan does not represent the number of covered lives; some Regional plans will have more patient lives than National Plans.

Can our products have different coverage with the same Managed Care Plan?

- Yes they can. Remember that the managed care plans can create a health benefit including pharmaceutical coverage for employers in a variety of ways. This means that some patients within a certain managed care plan may require a Prior Authorization for our products while some other patients who work for a different employer within that same managed care plan could have coverage for our products with no Prior Authorization.

Note: Formulary Grid Sheets are for your educational purposes only and are not to be used as promotional pieces or shown to your healthcare providers. An example of the Formulary Grid Sheet is included at the end of this section.

Formulary Grid

Grid Sheet Reimbursement Guide

Formulary Status Update

PRODUCT LEGEND: NF/C = Not on Formulary but Covered Benefit, F = On Formulary-Not Restricted,
P = On Formulary-Preferred, PA = Prior Authorization

Last updated: [illegible]

Account	Formulary/Benefit				Products	
Plan Name / Location	# Plan Lives	Open / Closed / Tiered Arr	% Plan Lives	Copay Ranges	PROVIGIL	PRIOR AUTHORIZATION GUIDELINES / COMMENTS
REGIONAL PLANS						
CDPHP (Capital District Phys.)	356K	3 tier	100%	20-35	PA	PA required for Narcolepsy, OSA, SWSD (Tier 3 copay). All other requests will be handled on a case by case basis.
ConnectiCare-CT	280K	3 tier	100%	10-30	PA	PA required for Narcolepsy, OSA, SWSD (Tier 3 copay).
Empire BCBS-NY	2.5M	3 tier	100%	10-35	PA	PA required for Narcolepsy, OSA, SWSD, Parkinson's, MS Fatigue, ADHD
Empire SHIP Program (NY State Employees)					PA	PA required for Narcolepsy and OSA.
Excellus Health-NY	482K	Open	80%	5-35	PA	PA required for Provigil-Criteria for narcolepsy, fatigue associated with MS, and depression, OSA and SWSD
	150K	Closed	20%	25	PA	Same as above
GHI	3M	3 Tier	100%	5-40	PA	PA required for Narcolepsy, OSA, SWSD (Tier 3 copay)
Health Now-NY (BCBS of Western NY, Northeastern NY, Central NY)	795K	3 tier	100%	10-25	PA	PA required for BiPolar, Major Depression, ADHD and GAD
HIP-NY	517K	Closed	100%	5-30	PA	Provigil PA approved for Narcolepsy: Appeal \ Denial Demonstrate Medical Necessity
Independent Health Plan	408K	3 tier	100%	7-30	PA	PA required for Narcolepsy, OSA, SWSD unless a Neurologists or Pulm.
MVP Health Care	100K	2 tier	40%	10-20	PA	criteria not disclosed at this point
MVP Health Care	150K	3 tier	60%	40	F	covered at Tier 3 copay
Oxford Health Plan-NY	971K	3 tier	100%	10-35	PA	Provigil is PA to narc, IH, OSA and SWSD. Sleep studies required
MEDICAID BY STATE						General Web Site
Connecticut	325K	Closed	100%	0	C	www.ctmedicalprogram.com
						covered for hypersomnolence syndromes of childhood, cataplexy and narcolepsy, drug induced organic personality disorder, organic affective syndrome, major depressive disorder (single episode), major depressive disorder (recurrent episode), atypical depressive
New York	3.5M	Closed	100%	0	PA	Medicaid Pharmacy and Therapeutics Committee - New York State Department of Health
						standard clinical questions will be used in the prior authorization review process and an additional clinical question for Provigil - Is the patient being treated for ES associated with SWSD or as an adjunct to OSA?
NATIONAL PLANS						
Aetna - CT	26K 180K	Closed 3 Tier	20% 80%	$10-$50 $10-$50	PA NF/C	Provigil PA approved for Narc, MSF, IH, OSA and TBI: See attached Criteria under Nat'l Plan Tab
Aetna - NY	8K 25K	Closed 3 Tier	20% 80%	$10-$50 $10-$50	PA NF/C	Provigil PA approved for Narc, MSF, IH, OSA and TBI: See attached Criteria under Nat'l Plan Tab
Wellpoint/Anthem CT	584K	3 tier	95%	10-50	F*&PA	Provigil approval criteria - Narc*MSFatigue\IH*OSA*alcoholic organic brain syndrome-SWSD; other uses need to be appealed 200mg max/day. *Sleep Study Required
Cigna - CT - Closed	28K	3 Tier	15%	5-30	PA	PA required for Provigil - MLN sufficient.
Cigna - CT - Tier	88K	3 tier	50%	10-50	NF/C	No PA Required - Provigil copay at 3 tier level
Cigna - CT - Rx Prime	61K	3 tier	35%	10-30	NF/C	No PA Required - Provigil copay at 3 tier level
Health Net of the Northeast-NY	77K	Tier 1	25%	5-15	PA	PA Criteria for Provigil - Dx narcolepsy & tried and failed 2 formulary agents unless pt has contraindication to the use of a stimulant; MS and FSS>4 and intolerant or failure of amantadine or FSS>4; OSA and ESS≥10 and CPAP for 2 months and an avg of ≥ 4
	45K	Tier 2	14%	15-30	PA	same as above
	180K	Tier 3	61%	30-40	PA or NF/C	same as above
Health Net of the Northeast-NY	14K	Tier 1	5%	5-15	PA	PA Criteria for Provigil - Dx narcolepsy & tried and failed 2 formulary agents unless pt has contraindication to the use of a stimulant; MS and FSS>4 and intolerant or failure of amantadine or FSS>4; OSA and ESS≥10 and CPAP for 2 months and an avg of ≥ 4
	56K	Tier 2	22%	15-30	PA	same as above
	107K	Tier 3	66%	30-50	PA or NF/C	same as above
United-CT	200K	3 Tier	100%	Varies	PA	Patient Specific PA Required. PA covered for Narc, I.H.S., MS Fatigue.
United NY	492K	3 Tier	100%	Varies	PA	Patient Specific PA Required. PA covered for Narc, I.H.S., MS Fatigue.

For Internal Use Only

Prior Authorization Forms

This section of your Reimbursement Process and Procedure Guide is a place for you to put copies of blank Prior Authorization Forms for specific plans that impact your customers. A few examples have been included.

You can provide the following information to the appropriate office personnel to help expedite the process.

- The Reimbursement Hotline Brochure. This brochure is an overview of the services available to assist in the Prior Authorization Process.
- A specific Managed Care Organizations website for the physician to request or download a Prior Authorization Form.
- Reimbursement Hotline Request/Consent to Release Medical Information Tear pad (see Appendix A and B)
- Blank Prior Authorization Forms can be provided only upon an unsolicited request from an HCP. These forms can be obtained from your National Account.

Please reference Sales Policy XI in the beginning of this document regarding dissemination of PA Forms for specific details.

Prior Authorization Forms-Example Only
Not for Detailing or Office Use

HUMANA.
Guidance when you need it most

Humana Clinical Pharmacy Review
1-877-486-2621 (Fax)
www.humana.com

Universal fax form for drug authorization

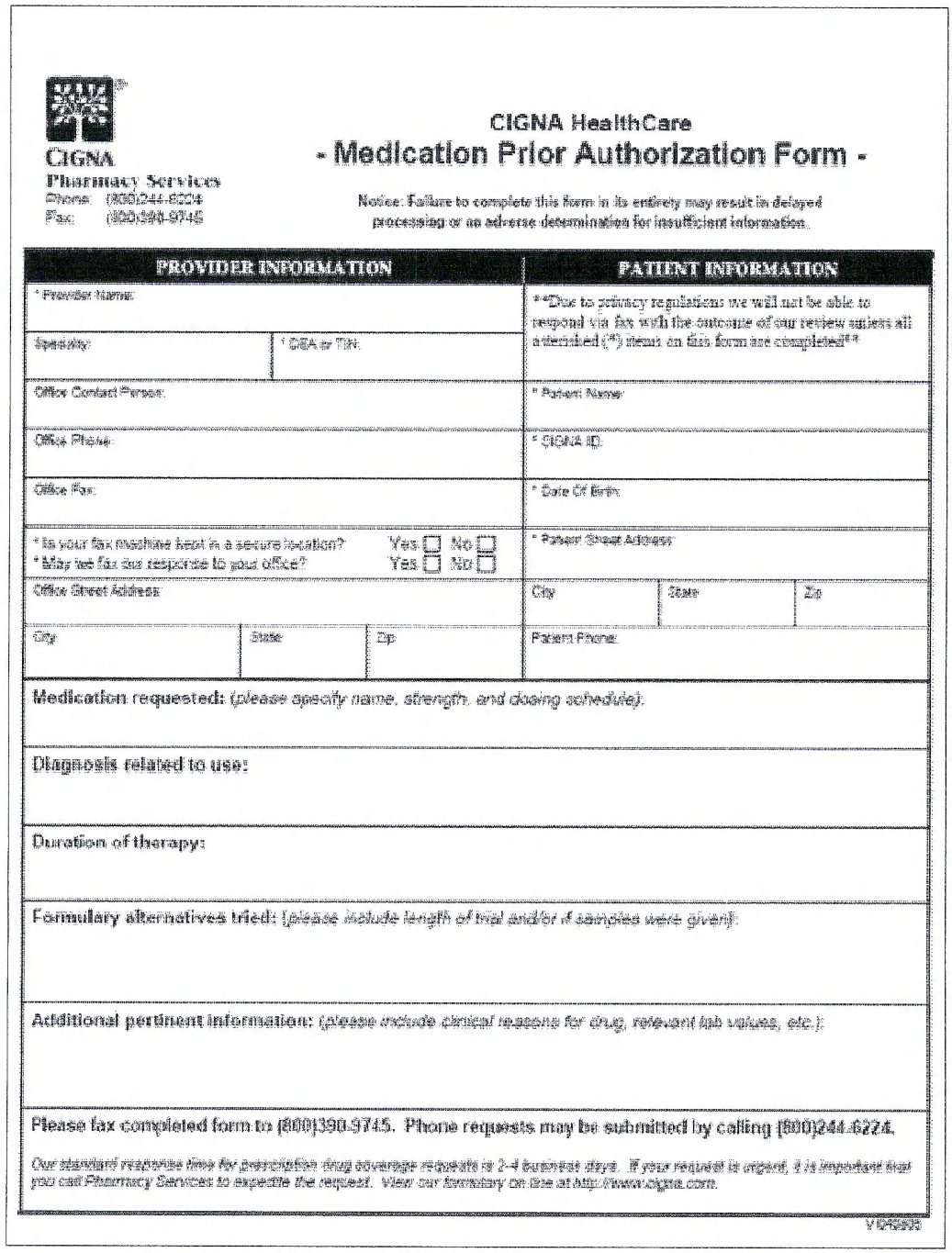
Patient Information				Physician Information			
Patient name:		Date of Birth:		Name:	TAX ID#:		
Sex: M ☐ F ☐	Home Phone: ( )	Work Phone: ( )		Address:	City	State	Zip code
Subscriber ID#				Telephone: ( )	Fax: ( )		
Address	City	State	Zip code	Physician Specialty (If applicable):			
Medication administered (if injectable): ☐ Physician office Will physician supply the medication? ☐ Yes ☐ No ☐ Patient's home ☐ Other _____				Physician signature (required):	Date:		

Diagnosis and Medical Information	
Is this a reauthorization? Yes ☐ No ☐	State from which you are requesting this medication (required):
Diagnosis:	Therapeutic alternatives previously used (required): _____ _____
ICD-9 Code: / J-Code:	Please list outcomes from previous treatment: _____
Please provide any medical information which may support approval:	
Note: Medications may be subject to a quantity limitation sufficient for a 30 day supply per fill based on FDA approved dosages.	

Medication and Date Requested
Medication requested:
Dosage:
Sig:

Prior Authorization of Benefits is not the practice of medicine or the substitute for the independent medical judgment of a treating physician. Only a treating physician can determine what medications are appropriate for a patient. Please refer to the applicable plan for the detailed information regarding benefits, conditions, limitations, and exclusions.

Please note any information left blank or illegible may delay the review process



CIGNA
Pharmacy Services
Phone: (800)244-6224
Fax: (800)390-9745

CIGNA HealthCare

- Medication Prior Authorization Form -

Notice: Failure to complete this form in its entirety may result in delayed processing or an adverse determination for insufficient information.

PROVIDER INFORMATION			PATIENT INFORMATION		
* Provider Name:			**Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all attempted (*) items on this form are completed**		
Specialty:	* DEA or TIN:				
Office Contact Person:			* Patient Name:		
Office Phone:			* CIGNA ID:		
Office Fax:			* Date Of Birth:		
* Is your fax machine kept in a secure location? Yes ☐ No ☐ * May we fax our response to your office? Yes ☐ No ☐			* Patient Street Address:		
Office Street Address:			City	State	Zip
City	State	Zip	Patient Phone:		

Medication requested: *(please specify name, strength, and dosing schedule)*:

Diagnosis related to use:

Duration of therapy:

Formulary alternatives tried: *(please include length of trial and/or if samples were given)*:

Additional pertinent information: *(please include clinical reasons for drug, relevant lab values, etc.)*:

Please fax completed form to (800)390-9745. Phone requests may be submitted by calling (800)244-6224.

Our standard response time for prescription drug coverage requests is 2-4 business days. If your request is urgent, it is important that you call Pharmacy Services to expedite the request. View our formulary on line at http://www.cigna.com.

Payer Share Reports

Payer Share Reports should help you understand the dynamics of the market by individual payer. These reports provide market share information for Cephalon products by payer segments on a National, Regional, Area, and Territory level. The market share segments include: Cash, Medicaid, Medicare Part D and Third party. .

Data included:

- Percent of Cephalon product business by payer segment
- Cephalon product market share within a designated market basket (i.e. stimulants, short-acting opioids, skeletal muscle relaxants)
- Payer's percent of total Cephalon product prescriptions
- TRx quarterly growth by payer The Payer Share Reports are distributed on a quarterly basis. The National Account Managers are available to provide guidance with interpreting the data about the top payers in your territory.

For ease of access and review, always keep a copy of the most current Payer Share Report with you. An example of the Payer Share Report follows.

Note: Payer Share Reports are for your educational purposes only and are not to be used as promotional pieces or shown to your healthcare providers. An example of the Payer Share report is included at the end of this section.

Payer Share Reports-continued

Example of a Payer Share Report

Payer Share Report							
Terr 12345678	% of Provigil Business	Segment	Terr 12345678	Area 12345	Region 123	Nation	
Apr 07 - Jun 07		Cash	13.00%	15.50%	13.71%	12.55%	
		Medicaid	5.55%	4.74%	2.97%	4.08%	
		Third Party	81.45%	79.75%	83.31%	82.37%	
		No Part D	72.51%	70.35%	74.57%	71.47%	
		Medicare Part D	8.94%	9.40%	8.84%	10.90%	
		Total	100.00%	100.00%	100.00%	100.00%	
	Provigil Market Share within Stimulant	Segment	Terr 12345678	Area 12345	Region 123	Nation	
		Cash	13.27%	15.19%	10.55%	10.81%	
		Medicaid	1.20%	1.12%	0.88%	1.54%	
		Third Party	7.58%	7.05%	6.06%	6.95%	
		No Part D	6.90%	6.38%	5.56%	6.26%	
		Medicare Part D	37.61%	32.19%	25.07%	24.03%	
		Total	6.12%	6.04%	5.41%	6.25%	

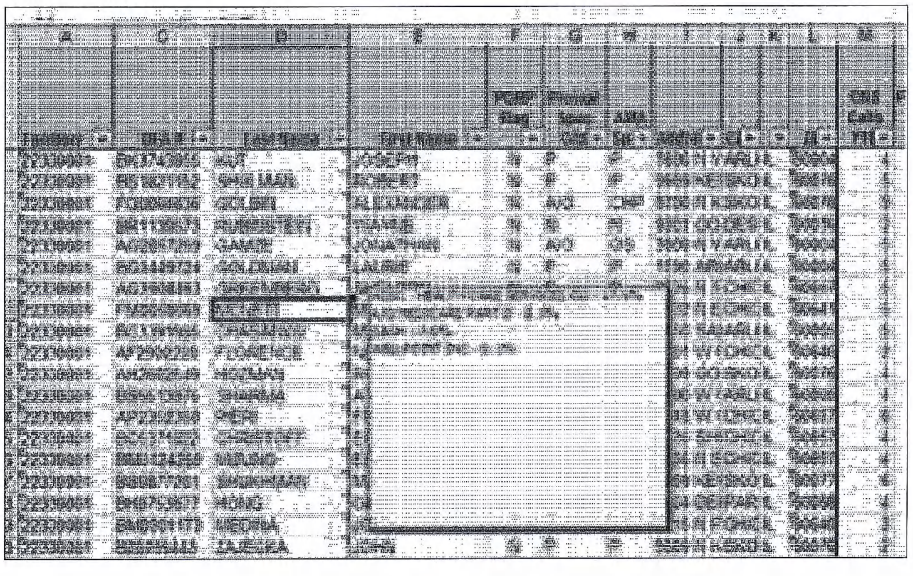
Plan	Payer's Percent of Total Stimulant Prescriptions	Payer's Percent of Total Provigil Prescriptions	Apr 07 - Jun 07 Provigil Market Share Territory 12345678	Apr 07 - Jun 07 vs Jan 07 - Mar 07 Growth	Apr 07 - Jun 07 vs Oct 06 - Dec 06 Growth	Apr 07 - Jun 07 Provigil Market Share Area 12345	Apr 07 - Jun 07 Provigil Market Share Region 123
MEDICAID	28.23%	9.59%	1.20%	43.65%	17.14%	1.12%	0.88%
BC/BS NORTH CAROLINA	16.21%	14.49%	5.63%	1.50%	-0.47%	5.65%	5.35%
CASH	6.00%	13.00%	13.27%	74.55%	152.63%	15.19%	10.55%
TRICARE MILITARY HLTH SVC SYS	4.24%	7.11%	10.27%	-13.22%	-10.26%	10.34%	9.17%
EMPLOYER GROUPS	3.76%	5.01%	8.16%	69.49%	-76.89%	7.32%	6.87%
A/O CLIENTS OF EXPRESS SCRIPTS/SCIP	2.59%	3.39%	7.99%	-15.25%	-39.02%	6.81%	6.77%
A/O CLIENTS OF CVS/CAREMARK CORP	2.12%	2.78%	7.32%	10.81%	10.81%	5.51%	6.44%
CIGNA HEALTHCARE	1.67%	2.11%	11.41%	36.29%	76.92%	6.94%	6.77%
A/O Medicare Part D	1.45%	8.94%	37.61%	1.56%	-3.65%	0.00%	0.00%
A/O CLIENTS OF CATALYST RX	1.21%	1.29%	6.48%	-17.39%	0.00%	9.86%	8.60%
A/O CLIENTS OF ARGUS HEALTH SYSTE	1.07%	1.15%	6.59%	-15.00%	-15.00%	5.40%	5.40%
A/O CLIENTS OF WELLPOINT PBM	1.00%	0.58%	4.13%	160.00%	29.09%	4.24%	3.16%

Prescriber Targeting Reports

The Prescriber Targeting Report provides prescription information to help target high potential prescribers. This report allows you the opportunity to qualify and quantify productivity of targets as well as non-called on prescribers. The report also shows prescribing activity for Cephalon products and products within the defined market. The report includes all data and Cephalon Speaker Program (CSP) information.

This report also details the top 10 payers for each target and the percentage each payer represents of the prescriber's total TRxs. These percentages are based on the Stimulant/Sedative Market for Provigil, the total Opioid Market for Fentora, and the Total SMR Market for Amrix. NOTE: A payer will only be listed it represents 120 TRxs or more in the past 6 months and a minimum of 5% share of the prescriber's total TRxs.

To access the top 10 Plans for a prescriber, simply hover over the last name of the prescriber and the payer detail will be displayed.



The payer information associated with the Prescriber Targeting Reports can assist with pre-call planning and targeting.

HIPAA
Health Insurance Portability and Accountability Act of 1996

Please note: *There is a full course about HIPAA on Ethics Connect. For more in depth information please refer to that section. However, below are the top ten things keep in mind about HIPAA.*

Top 10 Things to Remember about HIPAA

1. The Privacy Rule applies to the use and disclosure of protected health information (PHI).

PHI is individually identifiable health information that's transmitted or maintained in any format by a covered entity or business associate. This includes all oral, computer-based, and paper-based PHI. Individually identifiable health information is any information that (1) is created or received by a healthcare provider, covered entity, or employer; (2) relates to an individual's past, present, or future medical condition; providing healthcare to an individual; or payment for healthcare provided to an individual; and (3) identifies the patient or can be used to identify him.

2. The Privacy Rule applies to covered entities, which means certain healthcare providers and all health plans and healthcare clearinghouses.

A health plan is an organization that pays the cost of medical care. This includes health insurance companies, group health plans, HMOs, and government-administered programs such as Medicare and Medicaid. Healthcare clearinghouses, such as billing companies, process or facilitate the processing of healthcare transactions. Not all healthcare providers are covered by the Privacy Rule—it applies only to providers that electronically transmit PHI in connection with specified healthcare transactions. Fax transmissions and e-mail are not considered electronic transmissions under the rule.

3. The Privacy Rule also applies to a covered entity's business associates, which perform certain services or functions for the covered entity that involve PHI.

A business associate may perform a wide range of services for the covered entity that involve the use or disclosure of PHI, like data administration, accounting, management, legal services, consulting, claims processing, billing, quality assurance, operations management, or financial services. Sometimes covered entities act as business associates for each other. The government has indicated that to be considered a business associate, a business must provide services that relate to the covered functions of the covered entity—for example, those functions that make a hospital a healthcare provider.

Top 10 Things to Remember about HIPAA- continued

4. Patients have a right to be notified of a covered entity's privacy practices.
With certain exceptions, covered entities must provide written notice of their privacy practices to all patients, health plan enrollees, and anyone else who requests it, and the Privacy Rule specifies what information the notice must include. Healthcare providers in direct treatment relationships, such as doctors and nurses, must provide the notice to patients no later than their first appointment. The notice may be mailed, provided personally, or transmitted electronically (if the patient agrees). Healthcare providers in indirect treatment relationships, such as radiologists and pathologists, have to provide notice only if the patient requests it.

5. A patient may request restrictions on the use or disclosure of his PHI for treatment, payment, and healthcare operations.
A covered entity isn't required to agree to a restriction, but if it does, it must do what the individual requests—unless the individual needs emergency treatment and a healthcare provider needs restricted PHI to provide it. In that event, the covered entity must request that the healthcare provider not use or disclose the restricted information further once the emergency is over. The covered entity that agrees to a restriction must document it and keep it on file for at least six years from the date it was created or last in effect, whichever is later.

6. A patient generally has the right to inspect and copy PHI used to make healthcare or other decisions about her.
But certain exceptions apply, including exceptions for psychotherapy notes, information related to legal proceedings, and certain information regarding the operations of clinical laboratories. In certain circumstances, a covered entity may deny an access request, such as when access is likely to harm the individual or others. The individual may have a right to a formal review of the decision to deny access. If so, the review must be performed by a designated licensed healthcare professional who didn't participate in the original decision. Individuals must receive a written determination from the review within a reasonable time.

7. Patients generally have the right to request changes to their PHI.
If a covered entity agrees to such a request, it must make the amendment and inform the individual, anyone identified as having received the affected PHI, and any business associates. The covered entity may deny the request in certain situations, such as if it didn't create the PHI (and the creator still exists) or if it determines that the PHI is complete and accurate. Among other things, a denial must be in writing and explain the reasons for denial, the individual's right to submit a statement disagreeing with it, the associated procedures, and a statement of the individual's right to file a complaint.

Top 10 Things to Remember about HIPAA- continued

8. The Privacy Rule has a number of administrative requirements.
Covered entities must designate a privacy official and a contact person for patients; train all members of their workforce on PHI policies and procedures; establish administrative, technical, and physical safeguards to protect PHI; establish a complaint process and document all complaints; implement policies and procedures designed to comply with the Privacy Rule; and develop and enforce sanctions against employees who violate them.

9. The Privacy Rule generally preempts contrary state laws.
Exceptions to this rule include when the Secretary of HHS determines that a state law is necessary; when state law regulates the manufacture, registration, distribution, or dispensing of controlled substances; when state law requires reporting of disease, injury, child abuse, birth, or death; and when state law is more strict than the Privacy Rules—that is, when it provides greater privacy protection.

10. A simple violation of a single standard of the Privacy Rule is punishable by a civil fine of up to $100 per person per violation, with a cap of $25,000 per person for violations of a single standard in a year. Penalties rise to a criminal fine of up to $250,000 and/or imprisonment of up to ten years if a person intends to sell, transfer, or use the PHI for commercial advantage, personal gain, or malicious harm.

Appendix A: Details of the FENTORA™ Reimbursement Program

Callers may reach the FENTORA™ Reimbursement Program and the PAP by dialing the following toll-free number: 1-877-4 FENTORA (1-877-433-6867). The toll-free fax number is 866/495-0657.

The FENTORA™ Reimbursement Program and the PAP is available Monday-Friday from 9:00 am EST to 8:00pm ET. After hour calls will go to voicemail, and the call will be returned within one business day.

There are several materials available to assist with explaining services to your customer that can be ordered through Promotech:

FENTORA™ Reimbursement Program Request /Consent Form
FENTORA™ Reimbursement Program brochure

- The Reimbursement Hotline brochure that provides an overview of the services available to assist in the Prior Authorization Process.

- The Request/Consent to Release Medical Information Tear pads are designed to assist your offices with insurance verifications, prior authorizations, and appeals for their individual patients and should be faxed to the FENTORA™ Reimbursement Program. These forms are available for you to order from Promotech.

  - The Request Form/Consent to Release Medical Information Form gives the administrator of the FENTORA™ Reimbursement Program permission to release confidential medical information in order to conduct patient specific research with insurance companies. Physicians and/or office staff must have the patient sign the consent form and then fax a copy of this form to the hotline. The form also provides information necessary for hotline staff to initiate work on the case.

Appendix A: FENTORA™ Patient Assistant Program Overview

FENTORA™ Patient Assistance Program Overview

Physician's who are interested in enrolling a patient in the Patient Assistance Program (PAP) should contact the Reimbursement Hotline. The Reimbursement Hotline staff will screen patients to determine whether they are eligible for the PAP. Patients who are completely uninsured for prescription drugs may be eligible and are evaluated based on other criteria including:

- residency
- income
- not Medicare eligible

Eligible patients are enrolled in the PAP for a period of 12 months. Once enrolled in the PAP, the Reimbursement Hotline staff notifies the patients' physician and the FENTORA PAP distributor.

The Reimbursement Hotline facilitates re-enrollment at the end of the 12 month period, if the patient still requires FENTORA. If not, the patient's enrollment automatically terminates at the end of 12 months.

Appendix B: Details of the PROVIGIL® Reimbursement Hotline

Callers may reach the PROVIGIL® Reimbursement Hotline by dialing the following toll-free number: 800/675-8415. The fax number is 240/632-3811.

The PROVIGIL® Reimbursement Hotline is available Monday-Friday from 9:00 am EST to 8:00 pm EST. After hours calls will go to voicemail, and the call will be returned within one business day.

There are several materials available to assist with explaining services to your customer that can be ordered through Promotech:

- **PROVIGIL® Reimbursement Program Request /Consent form**
- **PROVIGIL® Reimbursement Program brochure**

The Reimbursement Hotline brochure. This brochure is an overview of the services available to assist in the Prior Authorization Process.

The Request/Consent to Release Medical Information Tear pads are designed to assist your offices with insurance verifications, prior authorizations, and appeals for their individual patients and should be faxed to the PROVIGIL® Reimbursement Program. These forms are available for you to order from Promotech.

- The Request Form/Consent to Release Medical Information Form gives the administrator of the PROVIGIL® Reimbursement Program permission to release confidential medical information in order to conduct patient specific research with insurance companies. Physicians and/or office staff must have the patient sign the consent form and then fax a copy of this form to the hotline. The form also provides information necessary for hotline staff to initiate work on the case.

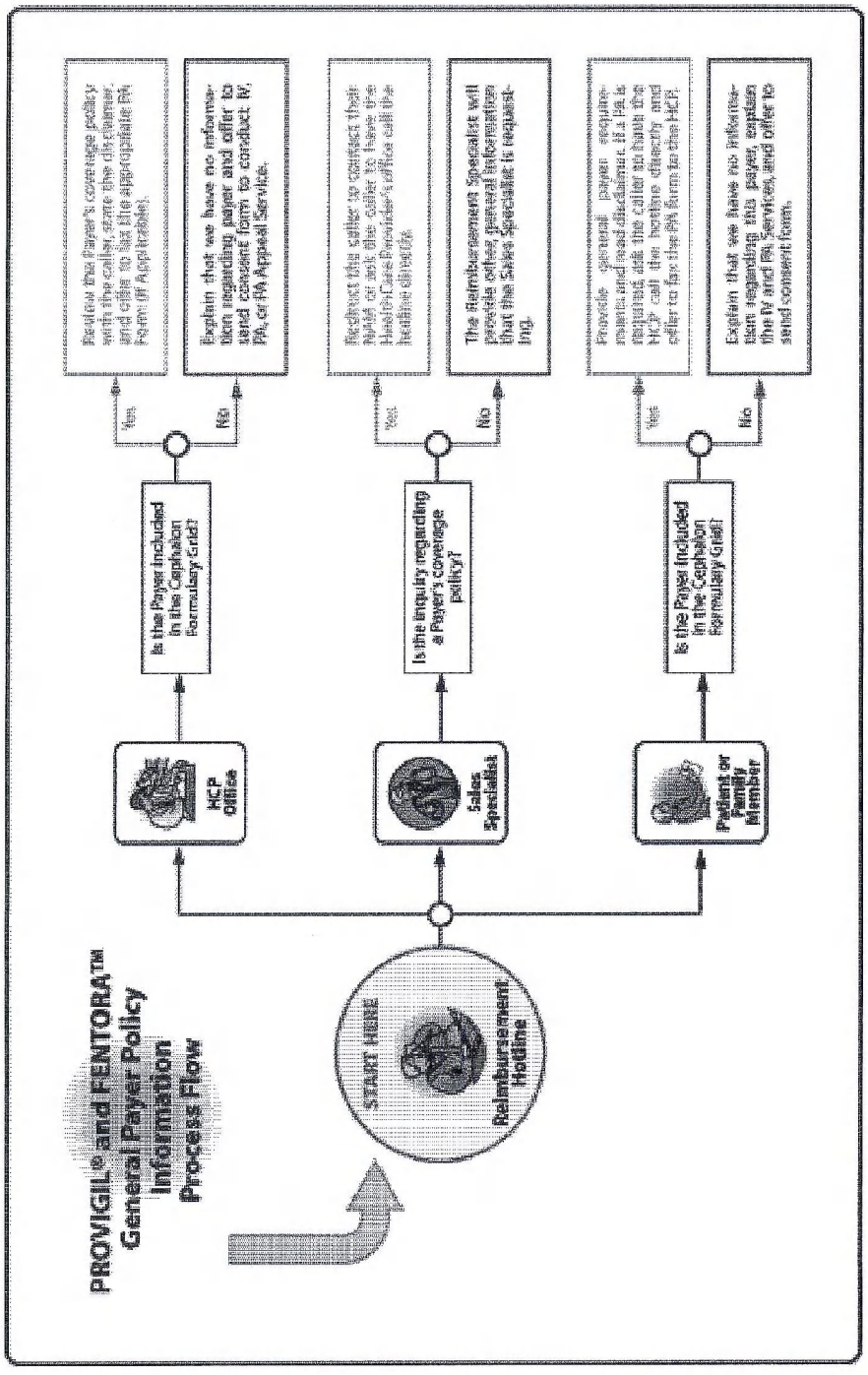
Appendix B: PROVIGIL®
Patient Assistance Program Overview

PROVIGIL® Patient Assistance Program Overview

Physician's who are interested in enrolling a patient in the Patient Assistance Program (PAP) should contact the Reimbursement Hotline. The Reimbursement Hotline staff pre-screen patients to determine whether they meet the insurance criteria. Patients who are completely uninsured for prescription drugs may be eligible and are referred to the National Organization of Rare Diseases (NORD) the administrator of the PROVIGIL Patient Assistance Program for further assistance.

NORD will mail an application for the PAP to the prospective patient within one business day of receipt of the request. Upon receipt of a completed application, NORD reviews the information to determine whether the patient is eligible. If the patient is approved they are enrolled for a period of 12 months. Approved patients are mailed PROVIGIL coupons (90 day supply). When the patient requires a refill they contact NORD.

Appendix C: General Payer Policy Information Process Flowchart



Managed Care Glossary of Terms

Sources: Department of Health and Human Services, Pholy's guide, Total Learning Concepts, BCBS, Pinsonault, Covance Market Access Services, Cephalon Managed Care Training for NAM's

A

Adjudication: Review process usually performed by a MCO or PBM to confirm or deny insurance coverage for a prescription claim.

Appeal: A formal request by an insured person or provider for reconsideration of a decision. There are two types of appeals: Internal and External. The internal appeal is the first step in the process if a Prior Authorization is denied. The physician may have more than one internal appeal opportunity based on the specific managed care plan's policy. In general, the internal appeal is physician-driven and the external appeal is patient-driven and can be submitted when the internal review options have been exhausted. However this may vary by state.

ASP (Average Sales Price): A pricing system based on manufacturer reported average sales prices that include manufacturer provided rebates, charge backs, and other discounts to purchasers. ASPs provide a more accurate measure of true acquisition costs.

AWP (Average Wholesale Price): This is an estimate of the wholesaler's price for a pharmaceutical product. It is established by the publisher (not the manufacturer) of the following certain publications including the Red Book, First Data Bank, Medispan, or other reference source.

B

Benefits: The services that members are entitled to receive based on their health plan.

Benefit Limitations: Any provision, other than an exclusion, which restricts coverage, regardless of medical necessity

C

Capitation: The method of payment in which the provider is paid a fixed amount for each person served (PMPM) no matter what the actual number or nature of services delivered.

Carve Out Benefit: Specific benefits which are administered separately from the rest of an organization's basic health insurance package. Examples of carve out benefits include mental health and substance abuse, dental, vision, and prescription drugs.

Case Management: Intended to improve health outcomes or control costs, services and education are tailored to a patient's needs, which are designed to improve health outcomes and/or control costs.

Managed Care Glossary of Terms
(Continued)

C-continued

CHAMPUS (Civilian Health and Medical Program of the Uniformed Services, also known as TRICARE): A health plan that serves the dependents of active duty military personnel, retired military personnel and their dependents. It was revamped as a managed-care system and renamed TRICARE, but still widely known under CHAMPUS.

Clinical Practice Guidelines: Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They define the role of specific diagnostic and treatment modalities in the diagnosis and management of patients. The guidelines contain recommendations that are based on evidence from a rigorous systematic review and synthesis of the published medical literature.

Closed Formulary: A "closed" formulary means that coverage is limited to products that are listed on the formulary. If a physician prescribes a non-formulary medication, an alternative formulary medication will be recommended when possible. In cases of medical necessity, non-formulary products are covered with prior authorization only.

CMS (Centers for Medicare & Medicaid Services): A US federal agency which administers Medicare, Medicaid, and the State Children's Health Insurance Programs.

Co-Insurance: A cost sharing requirement under a health insurance policy which provides that the insured will assume a portion or percentage of the costs of covered services.

Co-Pay: A cost-sharing arrangement in which a member pays a specified charge for a specified service (e.g., $10 for an office visit, $10 for a preferred /$25 for non-preferred prescription). The member is usually responsible for payment at the time the service is rendered.

D

Deductible: A fixed annual payment that a patient must make for medical services before any insurance reimbursement is available. The amounts vary widely by insurer and contract.

Diagnosis Related Groups (DRG): A system of classification for inpatient hospital services based on diagnosis, age, sex, and the presence of complications. It is used as a means of identifying costs for providing services associated with a diagnosis and as a mechanism to reimburse hospital and selected other providers for services rendered.

Disease Management: Programs for people who have chronic illnesses, such as asthma or diabetes, that try to encourage them to have a healthy lifestyle, to take medications as prescribed, and that coordinate care.

Managed Care Glossary of Terms
(Continued)

D-continued

DUR (Drug Utilization Review): A drug therapy evaluation and reporting process that tracks the prescribing patterns of individual physicians or groups of physicians in an effort to monitor safety, efficacy, and cost and to determine if the HMO/PPO provider(s) is/are complying with formulary guidelines, is/are over/under-utilizing certain medications, and is/are routinely writing for lower cost generics (rather than the most costly branded drugs). Incentives are often tied to formulary compliance.

E

Employee Retirement Income Security Act (ERISA): A Federal act, passed in 1974, that established new standards for employer-funded health benefit and pension programs. Companies that have self-funded health benefit plans operating under ERISA are not subject to state insurance regulations and healthcare legislation.

F

Federal Employee Health Benefit Program (FEP): Health insurance program for Federal workers and their dependents, established in 1959 under the Federal Employees Health Benefits Act. Federal employees may choose to participate in one of two or more plans.

FFS (Fee for Service): Also called traditional indemnity. FFS refers to a payment made to a healthcare provider for a healthcare service. In this type of reimbursement, the physician has no incentive to follow drug formulary protocols.

Formulary: A list of medications that a managed care company encourages or requires physicians to prescribe as necessary in order to reduce costs.

G

Gatekeeper: The person in a managed care organization, often a primary care provider, who controls a patient's access to healthcare services and whose approval is required for referrals to other services or other specialists.

H

Health Insurance Portability and Accountability Act (HIPAA): Also known as Kennedy-Kassebaum law, this guarantees that people who lose their group health insurance will have access to individual insurance, regardless of pre-existing medical problems. The law also allows employees to secure health insurance from their new employer when they switch jobs even if they have a pre-existing medical condition. The law also addresses the security and privacy of health data.

Managed Care Glossary of Terms
(Continued)

H-continued

Health Maintenance Organization (HMO): A health plan provides comprehensive medical services to its members for a fixed, prepaid premium. Members must use participating providers and are enrolled for a fixed period of time.

I

ICD 9 (International Classification of Diseases, 9th Edition): A coding system that includes codes for diagnoses and certain procedures.

Independent Practice Association (IPA): A group of private physicians who join together in an association to contract with a managed care organization.

Indigent Care: Care provided, at no cost, to people who do not have health insurance or are not covered by Medicare, Medicaid, or other public programs.

L

Letters of Medical Necessity (LMN): A key component in the successful completion of the reimbursement appeal process. Typically utilized after an initial prior authorization is denied, health plans may request that a physician provide additional supporting documentation in the form of a "patient appeal" or letter that includes a more detailed patient history.

M

MCO - Managed Care Organization: A healthcare organization or company that provides medical services to its membership through negotiated cost-saving managed healthcare practices.

Managed Care: A system of health care that combines delivery and payment; and influences utilization of services, by employing management techniques designed to promote the delivery of cost-effective health care.

Managed Pharmacy Benefit Program: A system in which a MCO includes the cost of prescription drugs as part of its healthcare coverage. It is often administered by a pharmacy benefit manager (PBM).

Medicaid: A federal program administered by states that provide medical benefits to low-income persons. Federal and state governments share costs. Medicaid eligibility criteria are state specific.

Managed Care Glossary of Terms
(Continued)

M-continued

Medically Necessary: Services or supplies that meet the following tests;

1) They are appropriate and necessary for the symptoms, diagnosis or treatment of the medical condition
2) They are provided for the diagnosis or direct care and treatment of the medical condition
3) They meet the standards of good medical practice within the medical community in the service area
4) They are not primarily for the convenience of the plan member or a plan provider
5) They are the most appropriate level or supply of service which can safely be provided.

Medicare: Medicare is health insurance for people age 65 or older, under age 65 with certain disabilities, and any age with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant). Medicare is administered by the Centers for Medicare and Medicaid Services (CMS). Medicare has the following parts:

- Medicare Part A (Hospital Insurance) helps cover inpatient care in hospitals. Part A also helps cover skilled nursing facility, hospice, and home health care.
- Medicare Part B (Medical Insurance) helps cover medically necessary services like doctors' services and outpatient care as well as some preventive services.
- Medicare Part C (Medicare Advantage Plans) is another way to get Medicare benefits. It combines Part A, Part B, and, sometimes, Part D (prescription drug) coverage. Medicare Advantage Plans are managed by private insurance companies approved by Medicare. These plans must cover medically-necessary services. However, plans can charge different copayments, coinsurance, or deductibles for these services.
- Medicare Part D—is a federal program to subsidize the costs of prescription drugs for Medicare beneficiaries in the United States. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and went into effect on January 1, 2006.

N

National Committee on Quality Assurance (NCQA): An independent national organization that reviews and accredits managed care plans and measures the quality of care offered by managed care plans.

Network: A group of affiliated contracted healthcare providers (physicians, hospitals, testing centers, rehabilitation centers etc.), such as an HMO, PPO, or Point of Service plan.

O

Open Formulary: An "open formulary" provides coverage for drugs not listed on the formulary. In this model, the benefit design structure does not differentiate between formulary and non-formulary drugs for payment purposes

Managed Care Glossary of Terms
(Continued)

P

P&T (Pharmacy & Therapeutics): Drug formularies are usually established by P&T Committees, comprised of consulting and plan physicians, pharmacists, and administrators of the Managed Care Organization.

Payer: The organization responsible for the costs of healthcare services. A payer may be private insurance, the government, or an employer's self-funded plan.

PCP (Primary Care Physician or Provider): A health care professional (usually a physician) who is responsible for monitoring, supervising, and coordinating an individual's overall health care needs, referring the individual for specialist care when necessary.

PDL (Preferred Drug List): This refers to drugs a plan or state Medicaid would like to be used first by a physician when deciding which drug to prescribe. Usually they are in place to help the plan save money.

PMPM (Per Member, Per Month): An amount that a healthcare professional is given each month for plan members in exchange for healthcare services.

Pharmacoeconomics: This refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. A pharmacoeconomic study evaluates the cost (expressed in monetary terms) and effects (expressed in terms of monetary value, efficacy or enhanced quality of life) of a pharmaceutical product. Pharmacoeconomic studies serve to guide healthcare resource allocation.

PBM (Pharmacy Benefit Manager or Pharmacy Benefit Management Company). A company that manages drug benefit programs for a managed healthcare plan.

Point of Service (POS): A type of insurance where each time healthcare services are needed, the patient can choose from different types of provider systems (indemnity plan, PPO or HMO). Usually, members are required to pay more to see PPO or non-participating providers than to see HMO providers.

PPO (Preferred Provider Organization): A managed healthcare plan that contracts with independent providers who agree to provide coverage.

Primary Care Provider (PCP): The health professional who provides basic healthcare services. The PCP may control patients' access to the rest of the healthcare system through referrals.

PA (Prior Authorization): A way in which physicians are able to obtain non-formulary products for their patients. For example, in a closed managed care formulary, physicians can prescribe only those drugs listed in the formulary and an emphasis may be placed on generic substitution and step therapy protocols. Access to non-formulary drugs is obtained through a prior authorization process.

Managed Care Glossary of Terms
(Continued)

R

Rebates: A pharmaceutical rebate is a deduction from an amount to be paid or a return of part of an amount given in payment. Rebates are usually part of contracts with MCO's.

Risk: The responsibility for profiting or losing money based on the cost of healthcare services provided.

S

Self-Funded Plan (Self-Insured Plan): Employer or organization assumes complete responsibility for health care losses of its covered employees. In this case, the employer does not pay premiums to an insurance carrier, but, rather pays administrative costs to the insurance company or health plan, and, in essence, treats them as a third party administrator.

Staff Model: A type of closed-panel HMO (where patients can receive services only through a limited number of providers) in which physicians are employees of the HMO. The providers see members in the HMO's own facilities.

T

Therapeutic Interchange: Therapeutic interchange is the procedure of dispensing prescribed medications that are chemically different but deemed therapeutically similar to the medication prescribed. In contrast, generic interchange is the process whereby a pharmacist dispenses a medication produced by another manufacturer that is the exact same chemical entity as the brand name product prescribed

Third Party Administrator (TPA): An organization that processes health plan claims but does not carry any insurance risk.

Tiered (incented) Formulary: A formulary that offers different types of drugs that are covered on different, or tiered, levels. Each tier has a different co-pay, which is the amount of money a patient pays out of pocket. The higher the tier, the higher your co-pay. The most common types are 2-tier and 3-tier prescription plans.

V

Verification of Coverage: Confirmation that a specific treatment is a covered benefit under an existing policy, usually before treatment is provided.

W

Worker's Compensation Coverage: States require employers to provide coverage to compensate employees for work-related injuries or disabilities.