# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Medication Guideline Review</td>
<td>2</td>
</tr>
<tr>
<td>Therapeutic Drug Monitoring: Anticonvulsants</td>
<td>3</td>
</tr>
<tr>
<td>Breathless: Current concepts in managing chronic obstructive pulmonary disease</td>
<td>5</td>
</tr>
<tr>
<td>Guidelines for Opioids in Chronic Non-Cancer Pain David Lyons, M.D.</td>
<td>7</td>
</tr>
<tr>
<td>COPD Tables</td>
<td>10</td>
</tr>
</tbody>
</table>
Chief Medical Officer’s Message by Charles Cho, M.D.

This quarterly Gold Coast Health Plan (GCHP) Pharmacy Newsletter brings you useful information for your practice including anti convulsants, COPD, and Guideline for Opioids in chronic non-cancer pain management. Dr. David Lyons covers the subject on opioids. He is an Internist who for more than 20 years has had special interest in treating patients with chronic pain. I hope his emphasis on utilizing long acting narcotics for chronic pain is helpful in managing these difficult problems.

Also, in this issue, I would like for you to pay special attention to the existing policy of the emergency supply of medicine. This obviates the situation in which your patients will not go without needed medicine. According to this policy, the pharmacist may dispense up to a ten (10) day supply of drugs when, in his/her clinical judgment this is warranted. This applies to off hours as well as weekends. In fact, the GCHP (Script Care) Pharmacy 24/7 line, 888-531-0998 is always available to assist pharmacists in this effort. This emergency provision of filling the needed drugs including refills, which you should be aware of, is very important, as none of your patients should have a lapse in supply of prescribed medications when needed.

Plan Guidelines: MEDICATION EMERGENCY OVERRIDE AVAILABLE 24 HOURS A DAY

Hospital Discharge Supply Authorization
If a request is received via phone, written prescription, verbal orders, or fax for a hospital discharge medication and the medication is not a covered drug, the Plan may approve up to a ten (10) day supply of medication(s) for continuation of hospital discharge therapy. For emergency override claims for hospital discharge medications pharmacies should call 1-888-531-0998 for authorization.

Emergency Supply Policy
If, in the pharmacist’s clinical judgment, the provision of an emergency supply of medication is warranted for a drug, the pharmacist should dispense up to a ten (10) day supply of medication(s).
Therapeutic Drug Monitoring: Anticonvulsants

Introduction:

The monitoring of therapeutic drugs involves measuring drug concentration plasma, serum, or blood. This information is used to individualize dosage so that drug concentrations can be maintained within a target range avoiding toxic ranges.

Drug concentration at the site of action cannot be routinely measured, but the desired or adverse effects may correlate better with plasma or blood concentrations than they do with dose. For a few drugs, concentration measurements are a valuable surrogate of drug exposure, particularly if there is no simple or sensitive measure of effect.

Which Drugs?

When an effect, such as changes in blood pressure, pain or serum cholesterol is readily measurable, the dose of a drug should be adjusted according to the response. Monitoring drug concentration is more useful when drugs are used to prevent an adverse outcome, for example achieving therapeutic levels or avoiding toxicity, as with anticonvulsants. A drug can satisfy certain criteria to be suitable for therapeutic drug monitoring. Examples include:

- Narrow target range
- Significant pharmacokinetic variability
- A reasonable relationship between plasma concentrations and clinical effects
- Established target concentration range
- Availability of cost-effective drug assay

At least one drug serum concentration level monitoring test is recommended for the prescribed anticonvulsant drug in one year. Although, frequency should be determined in the context of the individual patient and clinical outcome. If a patient receives multiple types of anticonvulsants, each anticonvulsant medication should be measured. A patient receiving an anticonvulsant drug(s) should have drug serum concentration level monitoring test within 180 days from start of medication therapy.
Anticonvulsant Therapeutic Drug Monitoring Serum Target Range:

- Phenytoin (Dilantin): 10-20 mg/L
- Carbamazepine (Tegetrol): 5-12 mg/L
- Sodium Valproate (Depakoate): 50-100 mg/L
- Lamotrigine (Lamictal): 1.5-3 mg/L
- Topiramate (Topamax): 2.0–5.0 ug/mL
- Phenobarbital: Infants and Children (<5) 15-30 ug/ML; Adults: 15-40 ug/ML
Breathless…Current concepts in managing chronic obstructive pulmonary disease

COPD is one of the most common problems in primary care, and a major cause of disability and death. These evidence-based recommendations can help optimize functional status.

The root of most evil:
Smoking is by far the most common cause of COPD. About 80% of smokers eventually develop COPD, and 20% do so rapidly. A small percentage of COPD cases are caused by occupational dust and fumes. The amount of tobacco smoked generally predicts the rate of pulmonary damage. Quitting can slow the loss of respiratory function, even in long-time smokers.

Managing stable disease:
Aggressive treatment can alter the natural history of the disease, and non-drug approaches are a vital foundation of therapy.

Smoking Cessation
Stopping tobacco use is the most effective single intervention to delay the development of COPD, slow the rate of decline in lung function, reduce the risk of exacerbations, and delay the onset of disability and mortality. It should be the cornerstone of management in smokers.

Even a brief intervention by a clinician can be effective for many patients. The key steps for brief intervention are the “5 As”:

- Ask: Identify tobacco users at every visit.
- Advise: Strongly urge all smokers to quit, using a clear, personalized message.
- Assess: Determine willingness to make a quit attempt.
- Assist: Help the patient develop a quit plan, including counseling, social supports, pharmacotherapy, and supplementary materials.
- Arrange: Schedule follow-up contact, in person or by telephone.

Pharmacological options to assist with smoking cessation include nicotine replacement therapy (gum, lozenges, patches, inhaled), bupropion (generic, Zyban, Budeprion, Buproban), and varenicline (Chantix). Smoking cessation is more likely to succeed when drug therapy is combined with other interventions such as education and behavior modification.
A clinical guideline, "Treating Tobacco Use and Dependence: 2008 Update", sponsored by the Department of Health and Human Services, describes treatments for tobacco dependence and provides information on quitting. It includes materials for clinicians and patients, and is available at: http://www.surgeongeneral.gov/tobacco/default.htm.

**Drug therapy**

Inhaled bronchodilators form the cornerstone of pharmacotherapy in stable COPD, supplemented when necessary with inhaled corticosteroids (ICS). Drug therapy can significantly improve symptoms, quality of life, lung function, and exercise performance, and reduce the frequency of exacerbations.

Inhaled bronchodilators (β-agonists and anticholinergics) are available as short- and long-acting agents. Combining bronchodilators of different pharmacologic classes may be more effective than increasing the dose of a single agent.

The benefit of therapy is best assessed by asking the patient -

- Is your treatment helping you?
- Is your breathing easier in any way?
- Can you do some things now that you couldn’t do before or do the same things faster?
- Do you get less breathless when you are doing the things you did before?
- Has your sleep improved?

Always ensure the patient knows how to use the inhaler device effectively and understands its purpose.

**Management at various stages of disease**

COPD is progressive, characterized by a steady decline in lung function and functional status that can be accelerated by acute exacerbations.

Managing exacerbations:
The downward progression in respiratory status for most COPD patients is often punctuated by acute decompensations requiring additional treatment. These should be addressed promptly and aggressively.

*(See Figures for COPD Guidelines at the end of the Newsletter)*

**References:**
1. American Thoracic Society, European Respiratory Society. Standards for the diagnosis and management of patients with COPD
Guidelines for Opioids in Chronic Non-Cancer Pain

David Lyons M.D.

Patients with chronic moderate to severe pain due to a variety of musculoskeletal conditions such as back pain, degenerative disc disorder, failed back surgery or arthritis derive clinical benefit from treatment with narcotics, many from long-acting (extended-release) narcotics.

Opioids are commonly prescribed for chronic non-cancer pain and maybe effective for short-term pain relief. However, when pain relief does not occur, short-term hydrocodone or oxycodone narcotics are used for an extended period of time, generally six months or much longer. This results in a common occurrence of the development of tolerance or dependence to the narcotics. Yet despite continued or accelerated use of these narcotics satisfaction of this approach for the chronic pain patients and their provider is often lacking and disappointing.

Guidelines for care of chronic non-cancer pain are currently based on the best available information. Treatment recommendations at this point cannot be defined specifically as a "standard of care".

Practice Recommendations

Following are my guidelines that I have had relative success with over the many years of my pain management practice. I recommend these guidelines to clinicians to consider when treating their patients.

• **Ask all patients about the inappropriate use of substances, including prescription opioids.**
• **Recommend pharmacotherapy for patients entering treatment for opioid dependence.**
• **Warn patients who are opioid dependent about the risk of accidental fatal overdose, particularly with relapse.**
• **Establish a Pain Contract**

For each of these patients receiving pain management an intake visit will be scheduled and the PCP will continue to provide non-pain related care. Since the majority of these patients have been treated by multiple providers with high or frequent doses of short-acting narcotics for an extended period of time, a majority of the patients will require long-acting narcotics. All efforts will be made to keep these patients out of the ER or urgent care. It is also important that cost control be emphasized by utilizing the concept of outcome only related referrals and imaging studies. A Pain Contract with the patient is an essential part of the success of the program.
The typical type of patient who has had pain for more than six months under the care of the PCP would have likely resulted in many cases becoming very time-consuming and frustrating and interfering with the PCPs office practice workflow. Most of these patients will have been utilizing three or more short-acting narcotics daily and often in a very dependent manner resulting in them taking a narcotic on a regular schedule, often with muscle relaxants or tranquilizers at the same time. Yet, frequently there is still a lack of satisfactory pain control despite narcotic tolerance and high doses of these narcotics. Despite obvious risk and concern about addiction, most patients with chronic pain even in the face of previous addiction history, need additional, sometimes personalized case management.

Continually reassess and monitor

It is essential to screen patients with chronic non-cancer pain before beginning long-term opioid therapy to identify those at risk for addiction. Increased risk of addiction should not necessarily rule out patients as candidates for long-term or long-acting narcotic therapy, but rather should dictate the frequency and intensity of monitoring during the course of treatment.

Screening tools

These patients should have ongoing visits to monitor the controlled use of the narcotics. Routine use of urine drug testing for patients on chronic opioids is recommended as there is evidence that urine drug screens can identify illicit opioid use or use of any other substance that otherwise is not prescribed or apparent to the treating physician.

Monitoring patients’ use of controlled drugs is critical in their care:

- Utilization of the prescription drug monitoring program (PDMP) also referred to as CURES online, allows authorized users to access patient controlled substance history at the point of care.
- Physicians can determine if the patient has been obtaining multiple prescriptions for pain medications from different physicians.
- Physicians can also determine if the patient is using multiple pharmacies or “Dr. shopping” in order to support their addiction to pain medications.
- You can determine if the prescriptions given to patients are being used to sell narcotics for profit.

Treatment Plans

Once a treatment plan is established, an essential effective part of the treatment program often includes using long-acting narcotics such as fentanyl transdermal, methadone, morphine sulfate extended-release (MSER) or other long-acting narcotics.
These medications can be available by utilizing the GCHP formulary and step therapy approach. Effectiveness in treating these patients includes limiting the short-acting narcotics to generally less than three times a day in most cases. This will avoid or reduce tolerance to narcotics. This is often very difficult since patients are looking for immediate relief from their pain or the feeling (euphoria) from the narcotics. The use of pain diaries can also be very effective in the ongoing treatment along with the required emphasis of adherence to the pain contract.

**In Summary**

A comprehensive approach for chronic pain management for Gold Coast Health Plan members is currently available through referral to Pain Management.

*Dr. Lyons may be contacted at:*

**Camarillo Office**
422-B Arneill Road
Camarillo, CA 93010
805-482-1282

**Oxnard Office**
2921 S. Saviers Road
Oxnard, CA 93033
805-487-5585
Algorithm for use of bronchodilator and inhaled corticosteroid (ICS) therapy in COPD

NOTES: If FEV1 is <50% predicated and exacerbations of COPD occur at least once within a year, consider adding ICS. Always ensure the patient can use an inhaled device effectively and understands its purpose.

If Limited Benefit
Add or substitute alternative class of lung-acting bronchodilator and/or add standing ICS

If Persistent Symptoms
Add standing long-acting agent (inhaled Beta-agonist or anticholinergic) to p.r.n short-acting agent

COPD Medication Choices

**Bronchodilators:** Are used to open and relax airways and help prevent shortness of breath.

- **Short-Acting:** They are considered first choice for treating stable COPD with intermittent symptoms. They include:
  1. Anticholinergics (ipratropium)
  2. Beta2-Agonists (albuterol and levalbuterol)
- **Long-Acting:** Used for persistent symptoms. They include:
  1. Anticholinergics (tiotropium and aclidinium)
  2. Beta2-Agonists (salmeterol, formoterol)

**Corticosteroids:** Available in both pill form or an inhaled form to prevent exacerbations. They may be used to treat Asthma.

**Expectorants:** To relieve mucus (guaifenesin)

**Methylxanthines:** Restricted for severe cases of COPD. Generally not recommend due to serious side effects.

**Phosphodiesterase-4 (PDE4) Inhibitors:** Are used to prevent COPD exacerbations. The only PDE4 inhibitor available is Roflumilast.