

## ALTERNATIVES FOR POTENTIALLY INAPPROPRIATE MEDICATIONS IN THE ELDERLY POPULATION: TREATMENT ALGORITHMS FOR USE IN THE FLEETWOOD PHASE III STUDY

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**Objective:** To provide estimates of the prevalence of potentially inappropriate medications used in eligible nursing facilities, to describe the development of evidence-based treatment algorithms for recommending safer alternative treatments to potentially inappropriate medications, and to provide the actual treatment algorithms developed for the Fleetwood Phase III study.

**Design:** Literature review, cross-sectional design.

**Setting:** Thirty North Carolina nursing facilities eligible for Fleetwood Phase III.

**Patients, Participants:** Algorithms developed for use by all pharmacists in the long-term care pharmacy serving the intervention facilities site for the Fleetwood Phase III study.

**Interventions:** Pharmacists are prospectively intervening directly with the prescriber to recommend a safer alternative to inappropriate medications using the standardized treatment algorithms developed for the study.

**Main Outcome Measure(s):** Prevalence of potentially inappropriate medications used among residents and the development of 14 treatment algorithms suggesting appropriate alternatives to inappropriate medications.

**Results:** The percentage of potentially inappropriate medications used ranged from 0% to 13.2% at baseline in March 2002. We also found that evidence-based treatment algorithms were well received by consultant pharmacists at the intervention sites of the Fleetwood Phase III study.

**Conclusion:** We have provided prevalence rates of potentially inappropriate medication use in nursing homes and developed treatment algorithms for pharmacists to use when making clinical recommendations regarding safer alternatives to potentially inappropriate medications in the elderly population. We are in the process of evaluating the effect of pharmacists' prospective interventions by using these standardized evidence-based treatment algorithms to reduce the prevalence of inappropriate medication use in intervention facilities.

**Key Words:** Adverse drug events, Fleetwood Phase III study, Geriatrics, Inappropriate medications, Nursing homes.

**Abbreviations:** ADE = adverse drug event, CMS = Centers for Medicaid & Medicare Services, DRR = drug regimen review, NTE = not to exceed.

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### INTRODUCTION

In the United States, elderly persons consume 31% of all medications prescribed;<sup>1</sup> the average nursing home resident uses six different medications, and 20% use at least 10 different medications.<sup>2</sup> Polypharmacy in this setting is problematic,<sup>3</sup> so much so, that the prescribing of potentially inappropriate medications has resulted in federal regulations to address the problem. An inappropriate drug is one in which the potential risks of taking the medication exceed the potential benefits derived from it. In many cases, a safer alternative may exist.<sup>4</sup> The use of potentially inappropriate medications can lead to complications in drug therapy, often manifested as an adverse drug event (ADE).<sup>5</sup> Indeed, Gurwitz et al.<sup>6</sup> estimated 1.89 ADEs per 100 resident-months, of which half were deemed preventable. The costs associated with medication-related problems has been estimated to be \$4 billion annually in United States nursing facilities,<sup>7</sup> and approximately 21,000 long-term care facilities provide care for more than 1.6 million people.<sup>8</sup>

Explicit criteria<sup>4,9</sup> for potentially inappropriate medication use have been used to estimate prevalence in nursing facilities,<sup>10-13</sup> with estimates ranging from 12%,<sup>10</sup> to 40%.<sup>11</sup> Current regulations from the Centers for Medicaid & Medicare Services (CMS) require that:

- The drug regimen of each resident be reviewed monthly by a consultant pharmacist
- The pharmacist report any "irregularities" to the attending physician and director of nursing
- These reports be "acted on"
- Each resident's drug regimen be "free of unnecessary drugs"

In response to concern regarding potentially inappropriate medication use in nursing homes, CMS has included a subset

of inappropriate medications, adapted from the Beers criteria<sup>9</sup> in the surveyor guidelines TAG 329<sup>14</sup> and TAG 428/429<sup>15,16</sup> (Table 1). Potentially inappropriate medications are classified as (1) “high severity” (high potential for severe adverse outcomes), which are assessed to determine compliance with the Unnecessary Drug requirement (TAG F329), and (2) “less severity” (high potential for less severe adverse outcomes), which are assessed to determine compliance with the drug regimen review (DRR) requirement (TAG F428/429). To the best of our knowledge, the effect of incorporating these TAGs into the survey process on the prevalence of potentially inappropriate medication use has not yet been studied.

### **FLEETWOOD PROJECT**

The American Society of Consultant Pharmacists (ASCP) Research and Education Foundation’s Fleetwood Project has been described in detail elsewhere.<sup>7,17,18</sup> In brief, the Fleetwood Project is a three-phase initiative to demonstrate the impact of consultant pharmacist services on improving patient outcomes and health care costs. Fleetwood Phase I consisted of conducting a pharmacoeconomic study to quantify the cost of medication-related problems in United States nursing facilities and quantitatively evaluate the value of consultant pharmacists’ services in reducing medication-related problems. The study found that DRRs conducted by consultant pharmacists save \$3.6 billion dollars annually by avoiding medication-related problems and increase optimal therapeutic outcomes by 43%. Fleetwood Phase II consisted of a feasibility study to test the application of the Fleetwood Model through prospective DRRs and formalized pharmaceutical care planning in elderly patients at highest risk for medication-related problems.

Fleetwood Phase III currently is underway. It aims to measure the effectiveness of the

Fleetwood Model in reducing potentially inappropriate medication use, potential adverse drug events, and undertreatment of common diseases in nursing facility residents. In sum, the Fleetwood Model is an innovative approach to the delivery of pharmaceutical care that incorporates prospective medication review, direct communication with the prescriber, and formalized pharmaceutical care planning for patients at highest risk for medication-related problems.

As part of the Fleetwood Phase III study, the long-term care pharmacy’s computer system was programmed to create a drug utilization review (DUR) alert. This alert would identify residents at highest risk for medication-related problems<sup>19</sup> (high-risk patient alert) and/or residents receiving a potentially inappropriate medication (inappropriate medication alert) at the time the medication orders are entered/verified by the pharmacist. Pharmacists are required to “act” on the inappropriate medication alerts by communicating directly to the prescriber on their recommendation for a safer alternative treatment. Recognizing that recommending alternative treatments for the clinically complex, typical nursing home resident is challenging, we sought to develop treatment algorithms for pharmacists to use when making clinical recommendations for safer alternatives to potentially inappropriate medications.

Consensus guidelines recommending possible alternatives to the use of potentially inappropriate medications have been reported,<sup>20</sup> yet not in the context in which the Fleetwood Project is being tested. The purpose of this paper is to provide estimates of the prevalence of potentially inappropriate medications used in the nursing facilities considered eligible for the Fleetwood Phase III study, to describe the development of evidence-based treatment algorithms for recommending safer alternative treatments to potentially

**TABLE 1. POTENTIALLY INAPPROPRIATE MEDICATIONS FROM SURVEYORS' GUIDELINES****"High Severity" Medications\***

Pentazocine

Long-acting benzodiazepines

Amitriptyline

Doxepin

Meprobamate

Disopyramide

Digoxin &gt;0.125 mg/d

Methyldopa

Chlorpropamide

GI antispasmodics (dicyclomine, hyoscyamine, propantheline, belladonna alkaloids, clidinium/chlordiazepoxide)

Barbiturates

Meperidine

Ticlopidine

**Diagnoses/Drug Combinations**

COPD—Sedative/Hypnotics

Gastritis, PUD, GERD—NSAIDs

Seizures/Epilepsy—metoclopramide

Blood clotting disorders—aspirin, NSAIDs, dipyridamole, ticlopidine

BPH—anticholinergic antihistamine/anti-Parkinson's/antidepressants, GI antispasmodics

Arrhythmias—tricyclic antidepressants

**"Less Severity" Medications\*\***

Phenylbutazone

Trimethobenzamide

Indomethacin

Dipyridamole

Reserpine

Diphenhydramine

Ergot Mesyloids (hydergine, cyclandelate)

Muscle relaxants (methocarbamol, carisoprodol, chlorzoxazone, metaxalone, cyclobenzaprine, dantrolene, orphenadrine)

Antihistamines (chlorpheniramine, diphenhydramine, hydroxyzine, cyproheptadine, promethazine, tripeleennamine, dexchlorpheniramine)

Diabetes—corticosteroids

Gastritis, PUD, GERD—Aspirin &gt;325 mg/d, potassium supplements

Seizures/Epilepsy—antipsychotics

Constipation—anticholinergic antihistamines/anti-Parkinson's/antidepressants, GI antispasmodics, narcotics

BPH—narcotics, propoxyphene, urinary antispasmodics (flavoxate, oxybutynin, bethanechol)

Insomnia—decongestants, theophylline, desipramine, SSRIs, methylphenidate, MAO inhibitors, beta-agonists

**Abbreviations:** BPH = benign prostatic hypertrophy, COPD = chronic obstructive pulmonary disease, GERD = gastroesophageal reflux disease, GI = gastrointestinal, MAO = monoamine oxidase, NSAIDs = nonsteroidal anti-inflammatory drugs, PUD = peptic ulcer disease, SSRI = selective serotonin reuptake inhibitor.

\*High potential for severe adverse outcomes.

\*\*High potential for less severe adverse outcomes.

**Source:** References 14–16.

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inappropriate medications, and to provide the actual treatment algorithms developed for the Fleetwood Phase III study.

## METHODS

The intervention arm of the Fleetwood Phase III study is based at the corporate office site of the Neil Medical Group pharmacy in Kinston, North Carolina, located about two hours from Raleigh-Durham. This pharmacy provides services to approximately 6,000 residents in about 50 nursing facilities, assisted living facilities, and group homes, though 90% of the facilities are nursing homes. The workload of consultant pharmacists is approximately 850 residents per month.

To be eligible for the Fleetwood Project, nursing homes had to receive pharmaceutical care from Neil Medical Group, have at least 50 Medicare/Medicaid certified beds, and service predominantly long-stay geriatric patients. The Neil Medical Group owns more than half of these nursing facilities; however, facilities not owned by Neil Medical Group are also eligible for the study. We identified 30 eligible nursing facilities in which we determined prevalent usage of inappropriate medications. Twenty-six of the 30 nursing facilities were enrolled in the study; 13 facilities served by Neil Medical Group's Kinston pharmacy will receive the intervention. The decision to provide the intervention at the level of the pharmacy was made to reduce the potential for cross-contamination. This effect would have biased the results toward the null.

## ESTIMATES OF PREVALENCE OF POTENTIALLY INAPPROPRIATE MEDICATION USE

During the initial stages of the Fleetwood Phase III study, a pharmacy-system software vendor created a field in the pharmacy drug record to "flag" patients prescribed potentially inappropriate medications. All medications listed in the Surveyor's Guidelines<sup>14-16</sup> were flagged (Table 1). We created one flag for res-

idents with either group of medications considered high or low severity, not distinguishing between the two. The flags evaluate PRN and standing orders only.

The pharmacy vendor provided an initial snapshot of the data covering a one-month period in March 2002 to estimate potentially inappropriate medication use. From these data, we estimated the prevalence of potentially inappropriate medications used through a cross-sectional study design. To evaluate the facility variation in the use of these medications, we estimated the prevalence for each of 30 nursing homes that represented the study base for the Fleetwood Phase III study.

## DEVELOPMENT OF TREATMENT ALGORITHMS FOR ALTERNATIVES TO POTENTIALLY INAPPROPRIATE MEDICATIONS

To develop the treatment algorithms, we conducted an extensive literature review to provide the basis for making alternative recommendations. The treatment algorithms are intended to serve as a "quick" reference for intervention pharmacists and aid in direct input in clinical decisionmaking. Initially, one of two of the authors (Christian, vanHaaren) with doctoral training in pharmacy developed a draft algorithm for each of the medications identified as potentially inappropriate. The authors discussed the rationale for the algorithms, as well as the evidence on which their recommendations were based. Revisions were made to the algorithms based on these discussions. The algorithms were then sent, with the supporting articles from the medical literature, to 10 practicing long-term care pharmacists in North Carolina employed by Neil Medical Group pharmacy and working at the intervention site for the Fleetwood Phase III study. The pharmacists (including both bachelor-trained [RPh] and doctoral-prepared pharmacists [PharmD]) provided review and recommendations for modification of the treatment algorithms. During

several conference calls, the rationale for suggested changes was discussed, and agreement was reached regarding the final treatment algorithms. During a conference call with members of the Fleetwood team, a geriatrician reviewed the algorithms for general content and likely effectiveness to enhance communication between pharmacists and physicians.

### IMPLEMENTATION OF THE ALGORITHMS

Neil Medical group developed training materials and conducted training programs for all pharmacists working in the Kinston, North Carolina, site (Table 2). Additionally, we created a pharmacist reference manual, which includes: an overview of the Fleetwood Project,<sup>18</sup> articles on potentially inappropriate medications in the elderly,<sup>4,9</sup> surveyors' guidelines,<sup>14-16</sup> handouts from the training programs, and treatment algorithms (Figures 2 to 16) with supporting references. The manual was distributed to all pharmacists and served as a useful reference and valuable training tool for new staff. Feedback from consultant and internal pharmacists at the intervention site pharmacy was voluntarily self-reported.

### RESULTS

#### ESTIMATES OF PREVALENCE OF POTENTIALLY INAPPROPRIATE MEDICATION USE

Among 30 nursing homes in North Carolina targeted for Fleetwood Phase III, the prevalence of potentially inappropriate medication use ranged from 0% to 13.2% at baseline (Figure 1); we will look for changes in the prevalence of use at the end of a 12-month follow-up period.

#### TREATMENT ALGORITHMS FOR ALTERNATIVES TO POTENTIALLY INAPPROPRIATE MEDICATIONS

Voluntary feedback from pharmacists at the intervention site pharmacy was received and indicates that evidence-based treatment algo-

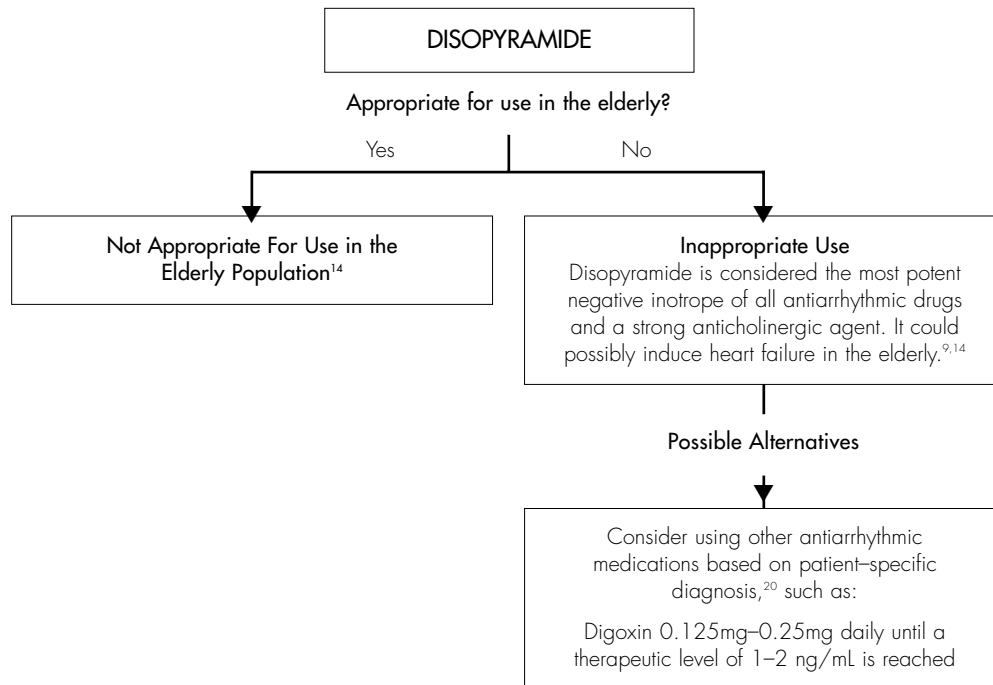
**TABLE 2. TRAINING PROGRAMS PROVIDED TO INTERVENTION PHARMACISTS IN FLEETWOOD PHASE III**

Common sense approaches to investigating potential adverse drug events
Medication appropriateness index
Drug-Drug interactions: implications for the elderly and some common scenarios
Improving communication with physicians, nurses, and patients
Potentially inappropriate medications
Depression in the elderly
Long-acting benzodiazepines
Digoxin use in the elderly
Hypertension in the elderly
Physical assessment

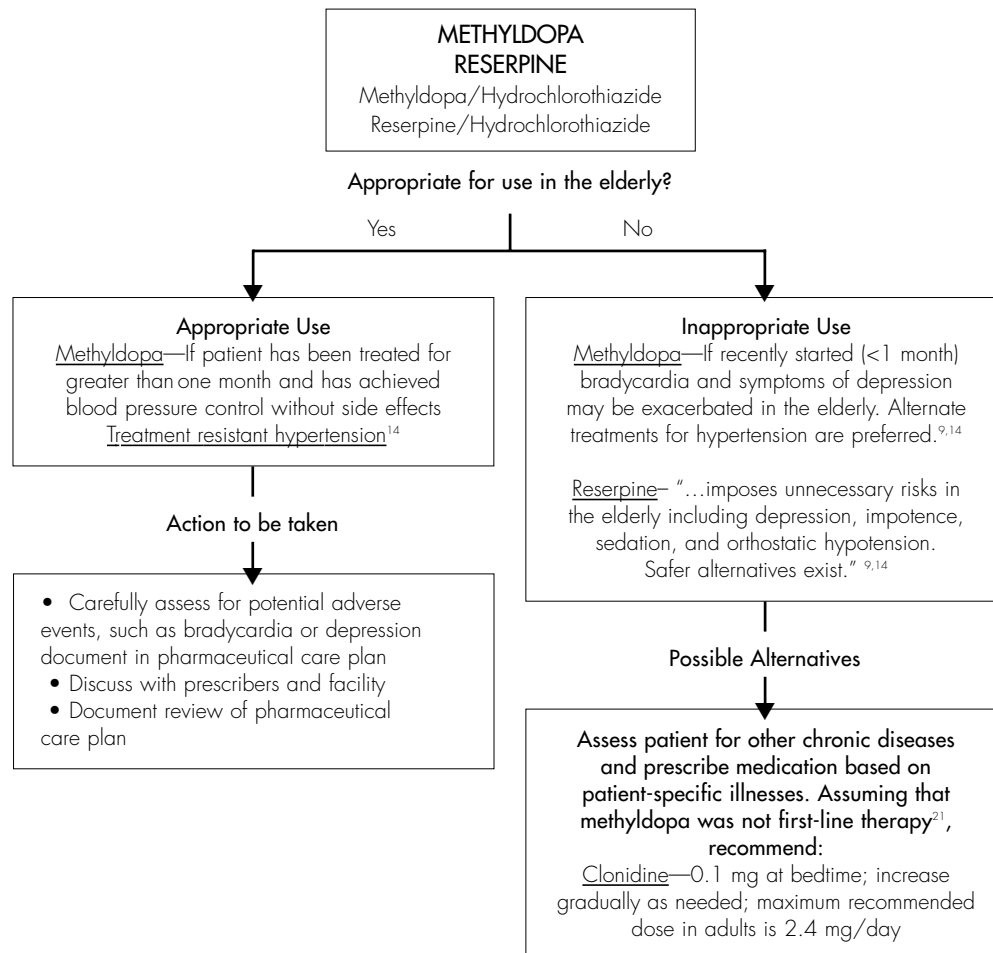
gorithms were well received, suggesting that implementation of these algorithms as a tool for consultant pharmacists to use in a clinical setting is feasible. Figures 2 to 16 provide the treatment algorithms for each of the targeted potentially inappropriate medications. For each, the algorithm provides information regarding when the medication might be used appropriately in the elderly population, and rationale for why and under what circumstances the medication is deemed as potentially inappropriate. If deemed as potentially inappropriate, possible treatment alternatives are provided. We identified relevant literature to support the recommendations for possible alternatives for the following specific medications or groups of medications included in the survey process: disopyramide,<sup>20</sup> antihypertensive medica-

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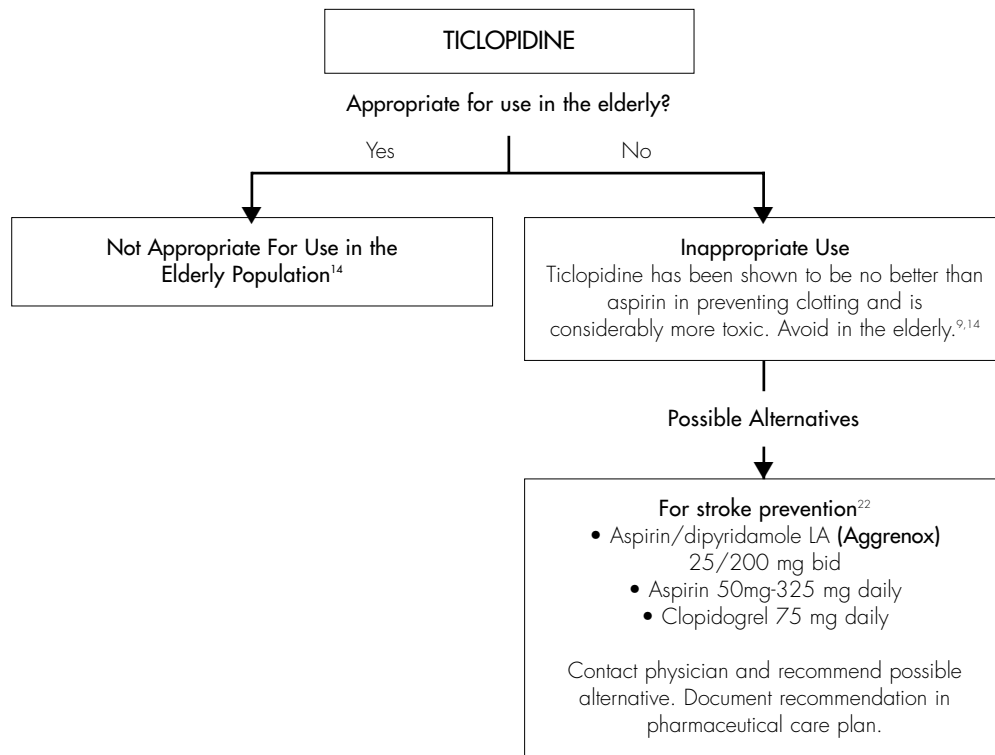
**FIGURE 2. ALGORITHM FOR DETERMINING APPROPRIATE USE OF DISOPYRAMIDE AND APPROPRIATE ALTERNATIVES TO CONSIDER IN A NURSING HOME POPULATION**



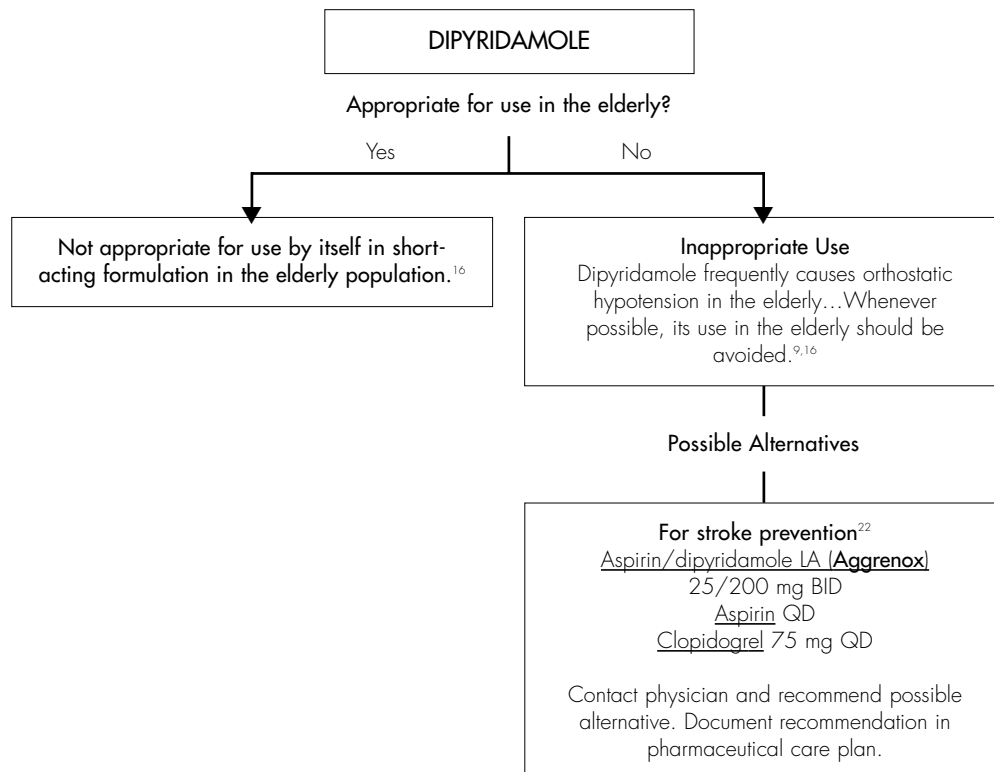
**FIGURE 3. ALGORITHM FOR DETERMINING APPROPRIATE USE OF METHYLDOPA AND RESERPINE AND APPROPRIATE ALTERNATIVES**



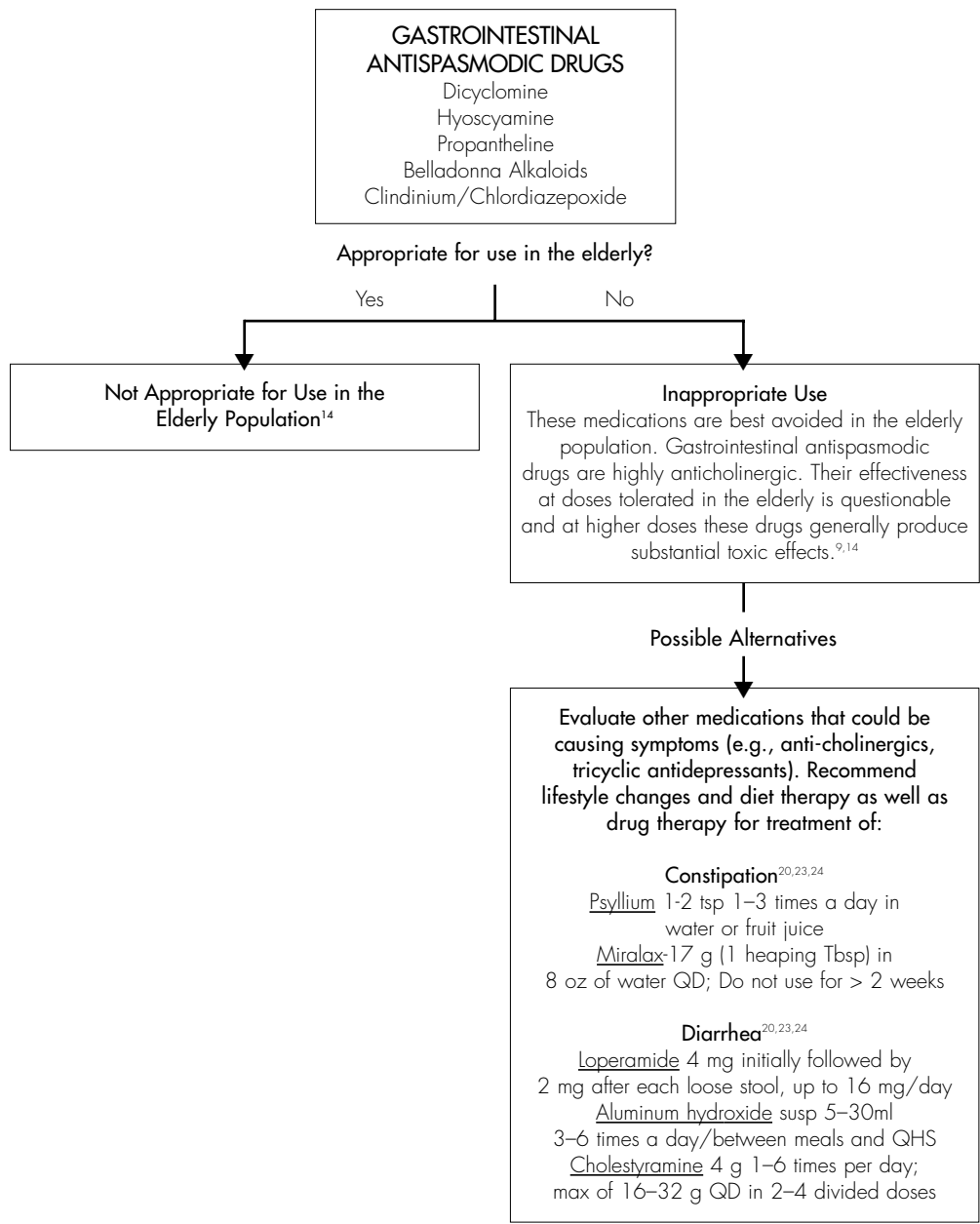
**FIGURE 4. ALGORITHM FOR DETERMINING APPROPRIATE USE OF TICLOPIDINE AND APPROPRIATE ALTERNATIVES**



**FIGURE 5. ALGORITHM FOR DETERMINING APPROPRIATE USE OF DIPYRIDAMOLE AND APPROPRIATE ALTERNATIVES**

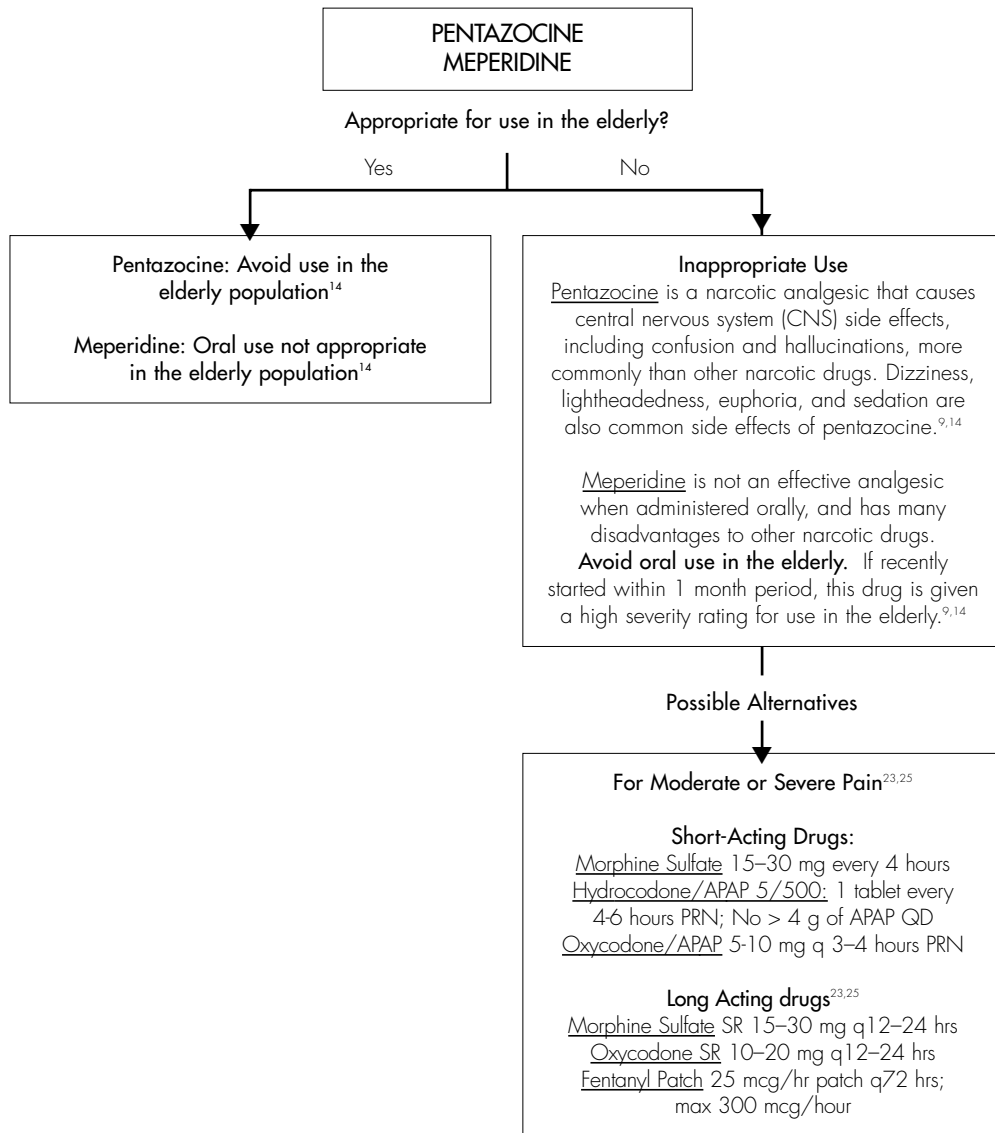


**FIGURE 6. ALGORITHM FOR DETERMINING APPROPRIATE USE OF GASTROINTESTINAL ANTISPASMODIC DRUGS AND APPROPRIATE ALTERNATIVES**

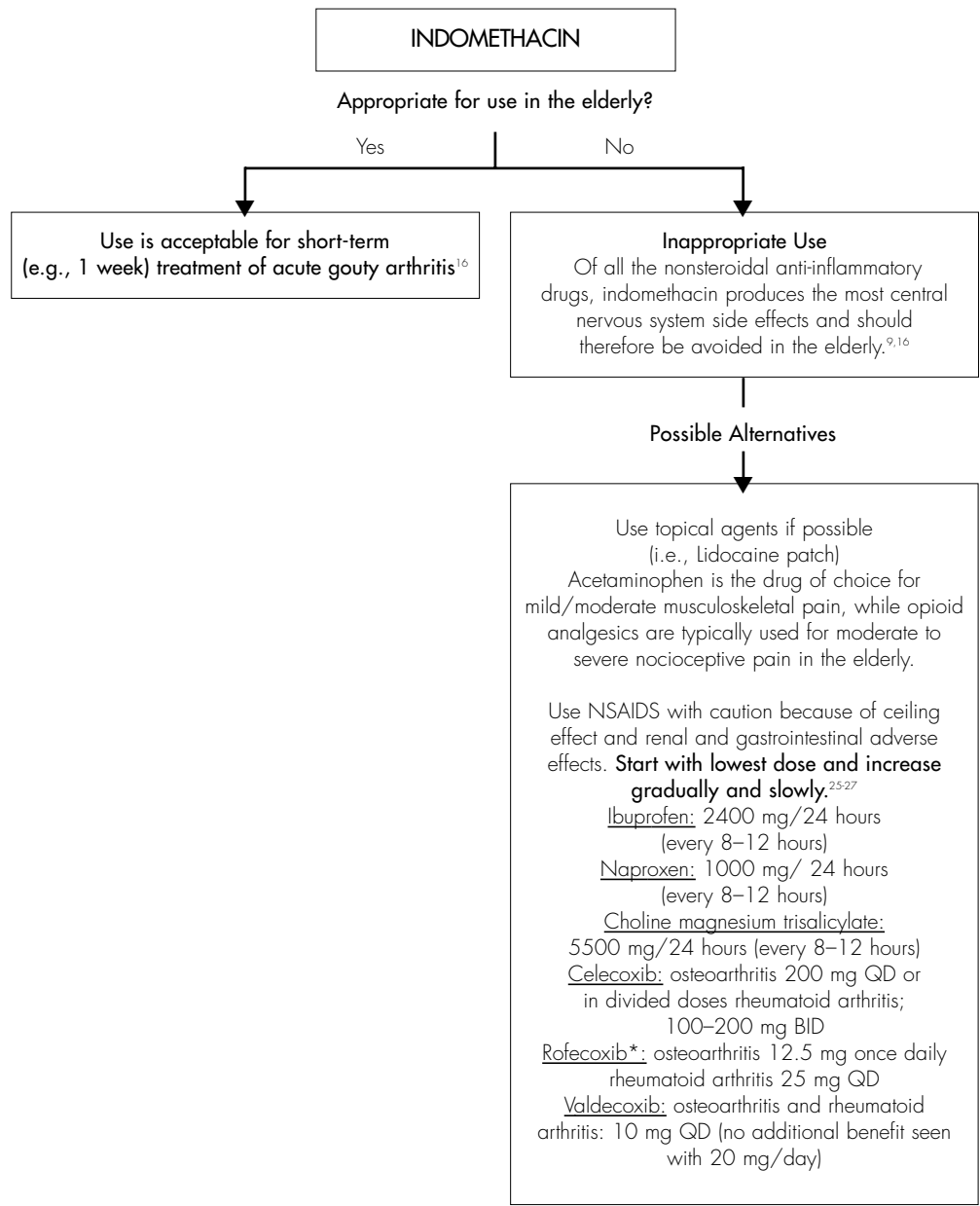




**FIGURE 7. ALGORITHM FOR DETERMINING APPROPRIATE USE OF PENTAZOCINE AND MEPERIDINE AND APPROPRIATE ALTERNATIVES**

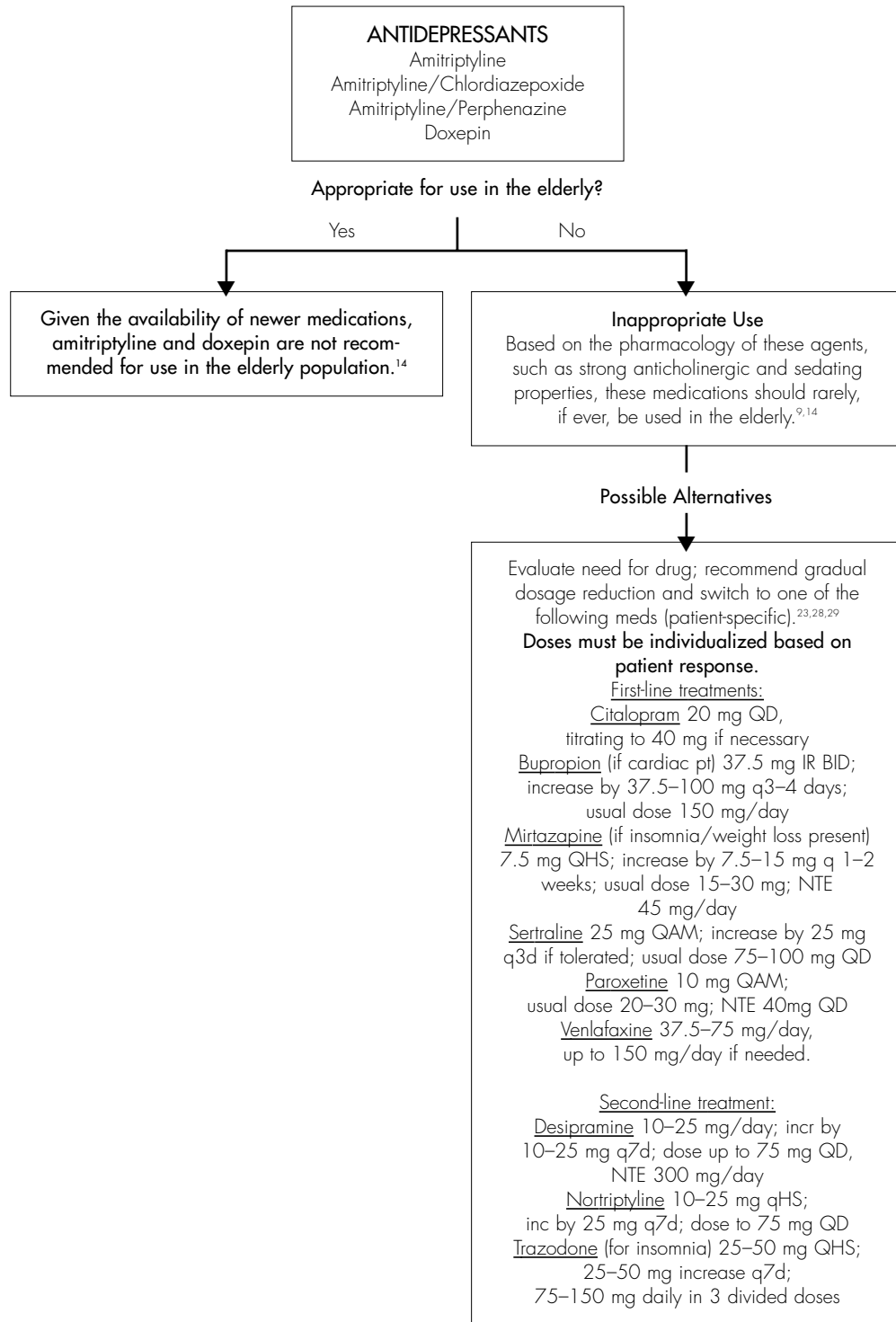


**FIGURE 8. ALGORITHM FOR DETERMINING APPROPRIATE USE OF INDOMETHACIN AND APPROPRIATE ALTERNATIVES**



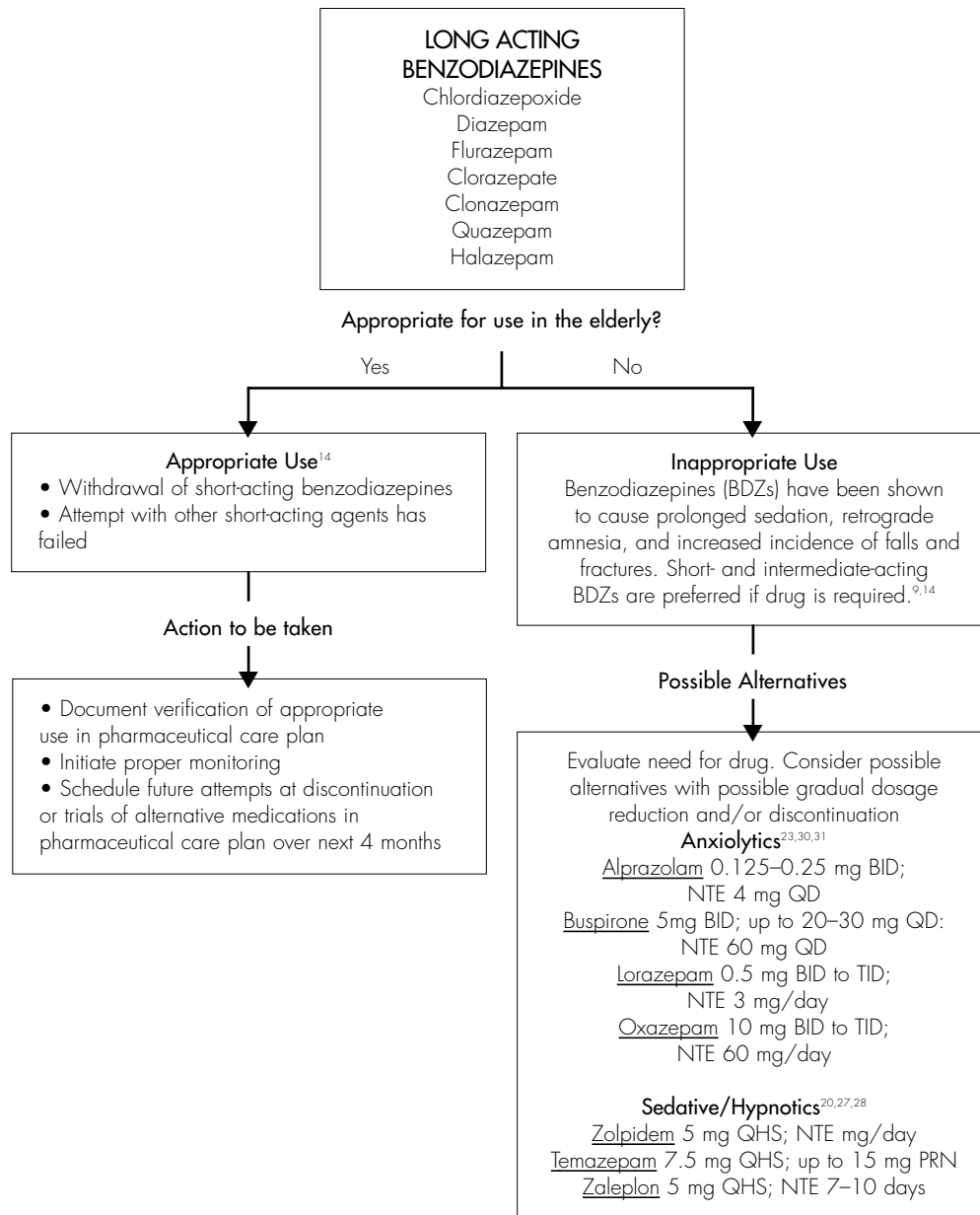
\*Drug removed from the market Oct. 2004

**FIGURE 9. ALGORITHM FOR DETERMINING APPROPRIATE USE OF AMITRIPTYLINE AND DOXEPIN AND APPROPRIATE ALTERNATIVES TO CONSIDER**

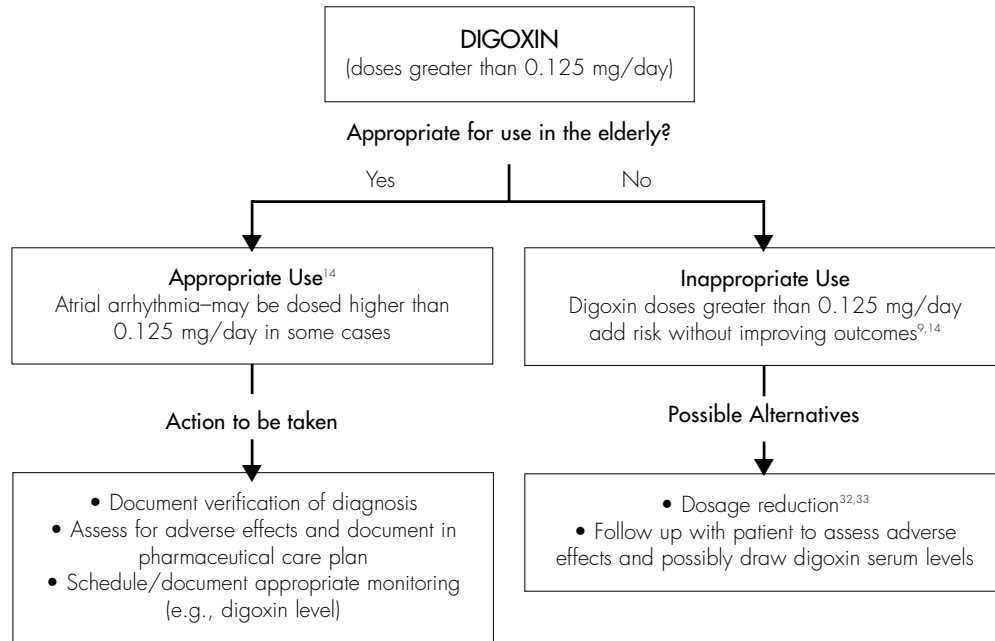
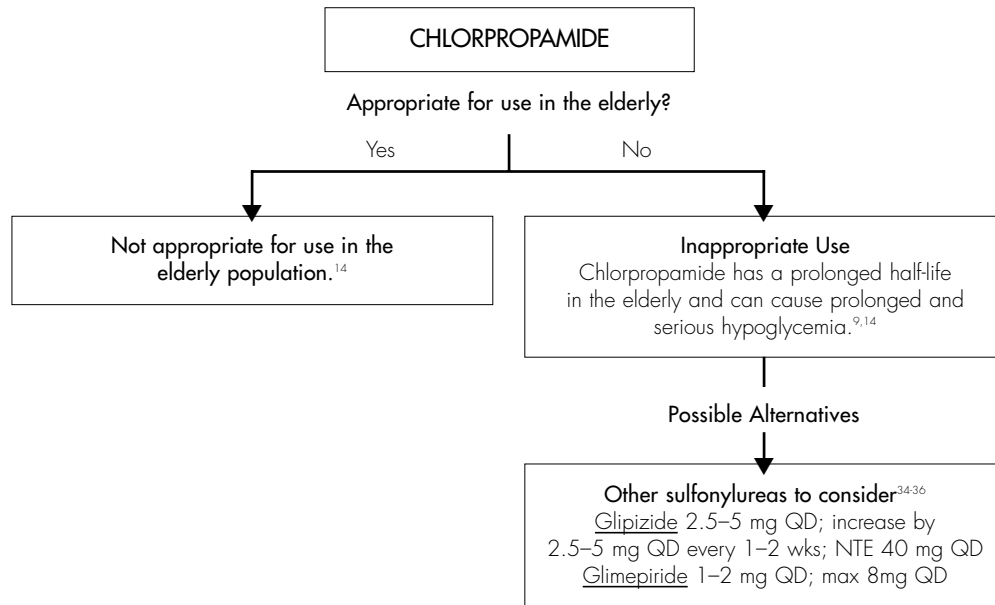


**Abbreviation:** NTE = not to exceed.

**FIGURE 10. ALGORITHM FOR DETERMINING APPROPRIATE USE OF LONG-ACTING BENZODIAZEPINES AND APPROPRIATE ALTERNATIVES TO CONSIDER**

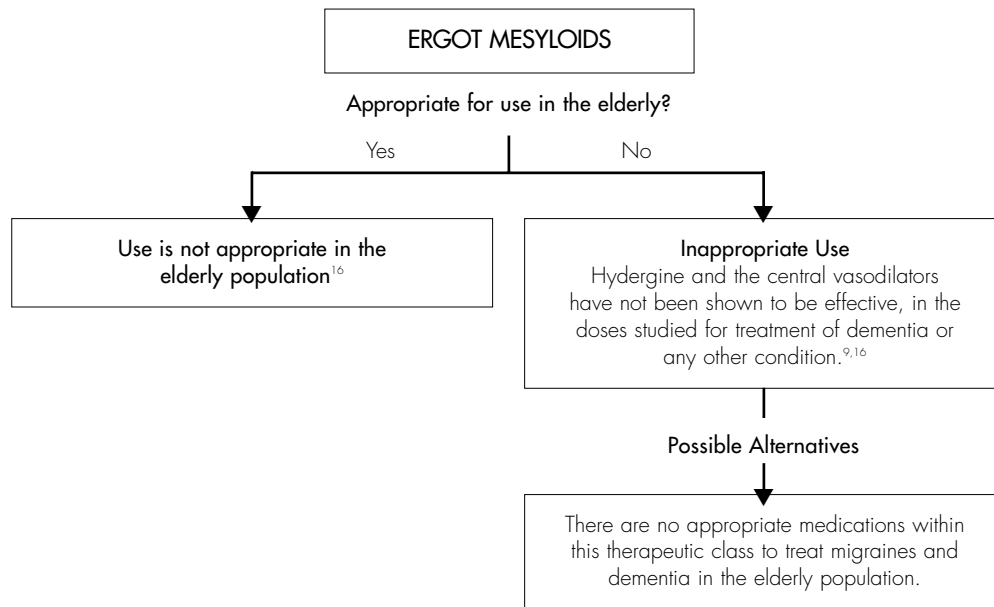


**Abbreviation:** NTE = not to exceed.

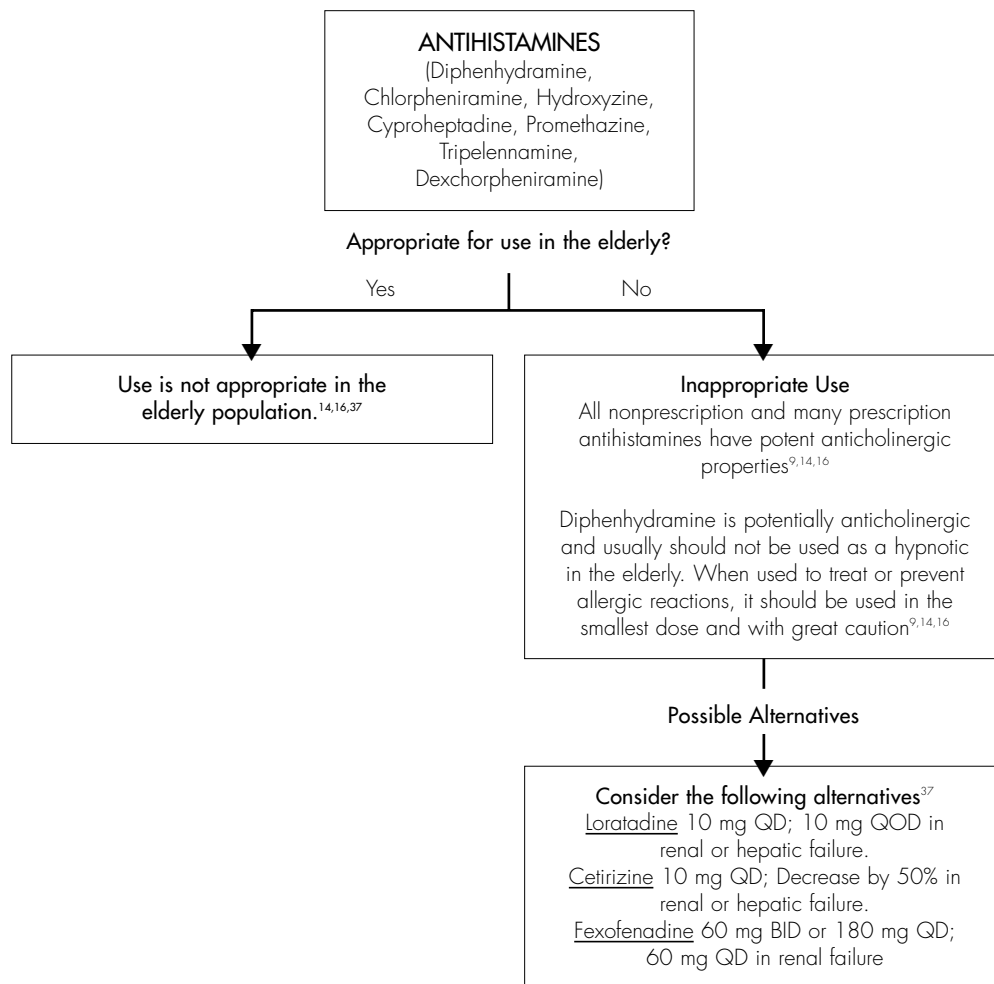
**FIGURE 11. ALGORITHM FOR DETERMINING APPROPRIATE USE OF DIGOXIN AND APPROPRIATE ALTERNATIVES TO CONSIDER****FIGURE 12. ALGORITHM FOR DETERMINING APPROPRIATE USE OF CHLORPROPAMIDE AND APPROPRIATE ALTERNATIVES**

Abbreviation: NTE = not to exceed.

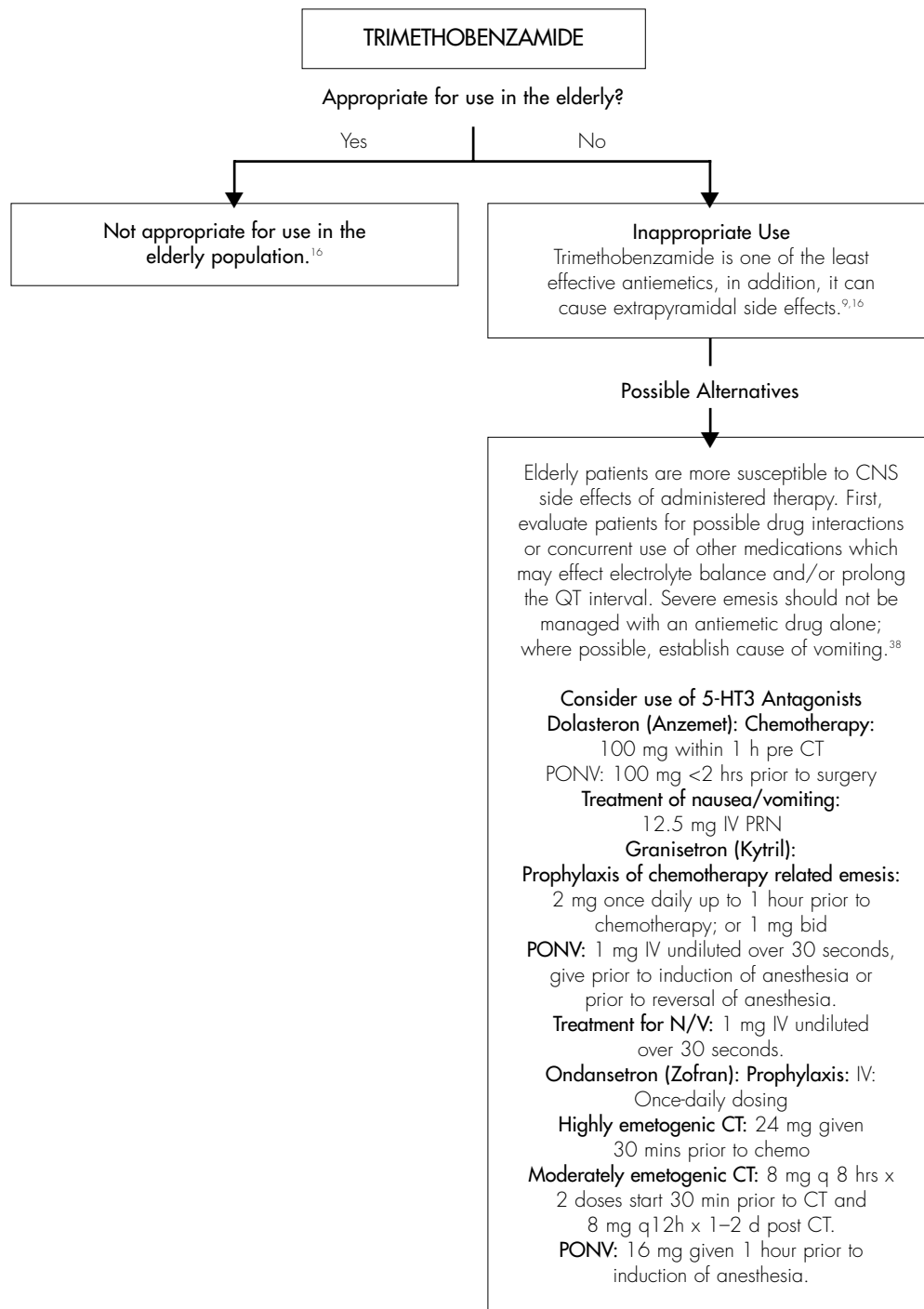
**FIGURE 13. ALGORITHM FOR DETERMINING APPROPRIATE USE OF ERGOT MESYLOIDS AND APPROPRIATE ALTERNATIVES**



**FIGURE 14. ALGORITHM FOR DETERMINING APPROPRIATE USE OF ANTIHISTAMINES AND APPROPRIATE ALTERNATIVES TO CONSIDER**

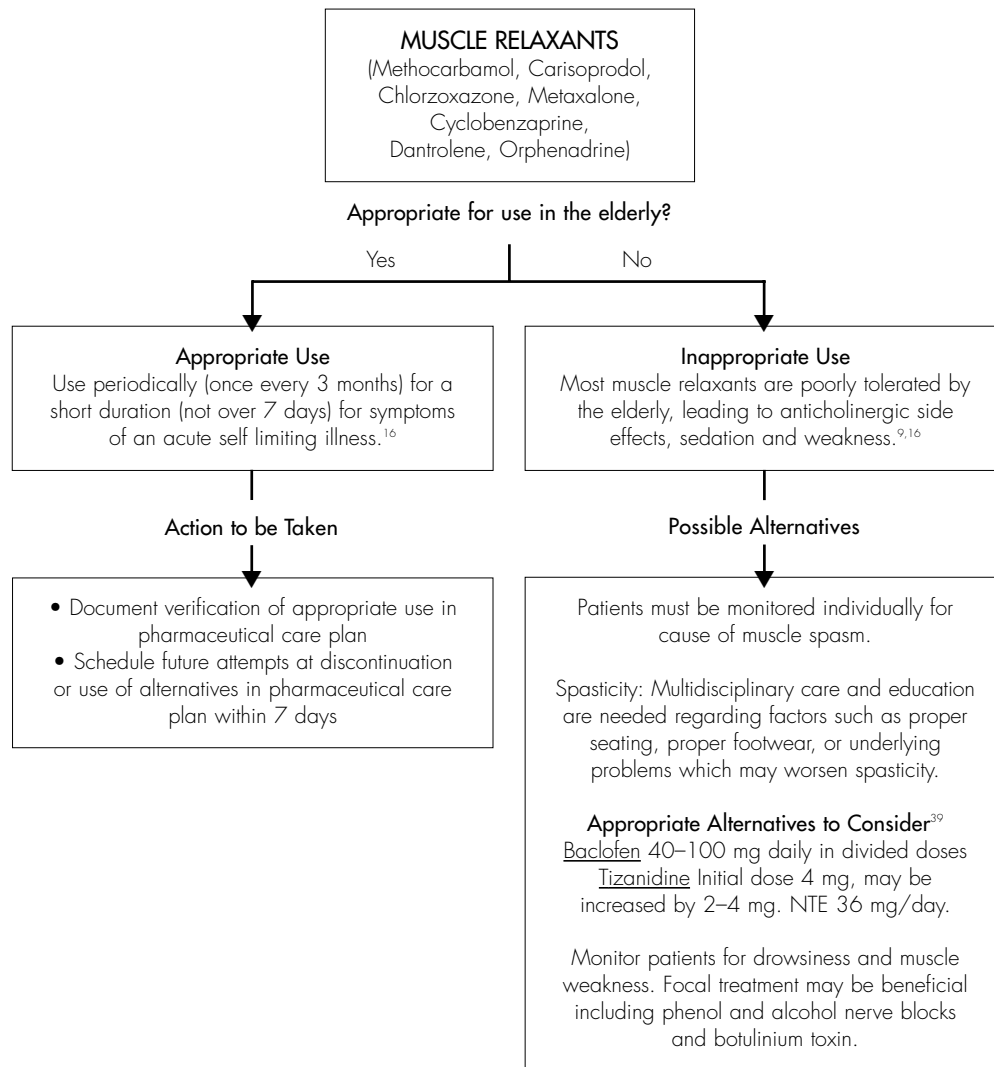


**FIGURE 15. ALGORITHM FOR DETERMINING APPROPRIATE USE OF ANTIHISTAMINES AND APPROPRIATE ALTERNATIVES**



**Abbreviation:** CT = Chemotherapy, PONV = Post-Operative Nausea/Vomiting.

**FIGURE 16. ALGORITHM FOR DETERMINING APPROPRIATE USE OF ANTIHISTAMINES AND APPROPRIATE ALTERNATIVES**



**Abbreviation:** NTE = not to exceed.



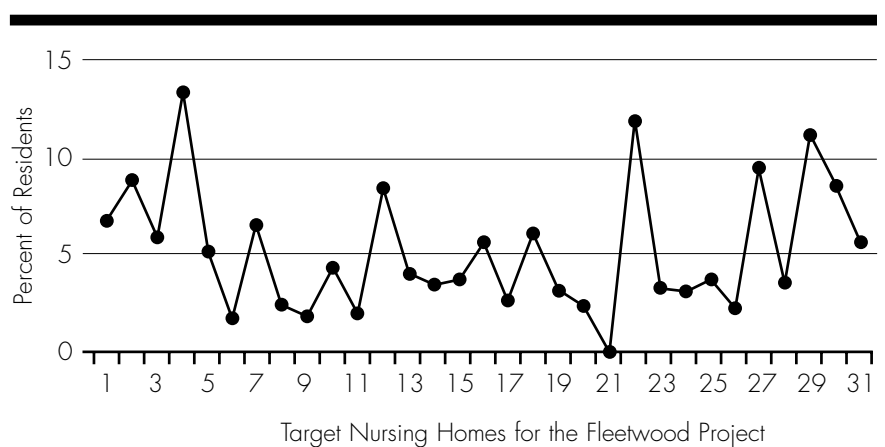
tions,<sup>21</sup> antiplatelets,<sup>22</sup> gastrointestinal antispasmodics,<sup>20,23,24</sup> analgesics management,<sup>23,25-27</sup> antidepressants,<sup>23,28,29</sup> long-acting benzodiazepines,<sup>30,31</sup> digoxin,<sup>32,33</sup> chlorpropamide,<sup>34-36</sup> antihistamines,<sup>37</sup> triethambenzamide,<sup>38</sup> and muscle relaxants.<sup>39</sup>

## DISCUSSION

We have provided prevalence rates of potentially inappropriate medication use in nursing homes and developed treatment algorithms for consultant pharmacists to use when making clinical recommendations regarding safer alternatives to potentially inappropriate medications in the elderly population. One of the specific aims of the Fleetwood Phase III study is to quantify the effect of the Fleetwood Model on reducing the prevalence of potentially inappropriate medication use, as well as reducing the occurrence of adverse drug events in the nursing home population. The algorithms described in this manuscript will assist in achieving these goals.

The prevalence of potentially inappropriate medication use was lower (albeit still prevalent) in our baseline data compared with reports published prior to the incorporation of a subset of federal regulations concerning potentially inappropriate medications in the survey process. While this may be a result of geographic variability, as noted by others,<sup>10</sup> or the effects of inclusion of such potentially inappropriate medications in the survey process, it is likely that the lower prevalence estimates are a function of only considering medications that are targeted by the survey process and not the complete list recommended by Beers.<sup>9,40</sup> This study was not designed to evaluate the effects of regulation on the use of potentially inappropriate medications in the nursing home. Admission to a nursing home has been thought to decrease the use of potentially inappropriate drugs,<sup>12</sup> with 16% of inappropriate medications discontinued within three months following

**FIGURE 1. PROPORTION OF RESIDENTS IN MARCH OF 2002 WITHIN TARGET NURSING HOMES TAKING POTENTIALLY INAPPROPRIATE MEDICATIONS**



admission.<sup>13</sup> Yet, in a study conducted prior to inclusion of a subset of these medications in the survey process, 18% of potentially inappropriate drugs were initiated in the three months after entry to nursing home.<sup>13</sup> This suggests that the use of treatment algorithms during a prospective DRR within nursing facilities may be useful.

The quality of medication prescribing and use in elderly people has been an important issue of substantial concern for policymakers, regulators, health care researchers, and the public.<sup>8</sup> What contributes to the use of potentially inappropriate drugs in nursing facilities? Factors related to use of medications deemed as potentially inappropriate include having multiple prescribers<sup>12,41,42</sup> and pharmacies,<sup>42</sup> and having a nonspecialist, nonurban male physician over the age of 50.<sup>12</sup> Infrequent physician visits and lack of formal training for nursing home health care professionals may also be contributing factors.<sup>9</sup> While many of these factors appear to be nonmodifiable risk factors for potentially inappropriate medication use, each suggests that systems-level changes may be effective.

The use of computerized DUR systems in

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nursing homes (such as the one being implemented as part of Fleetwood Phase III) is not novel. More than 10 years ago, Beers et al.<sup>41</sup> devised a system that estimated the frequency of inappropriate prescriptions and produced written, educational statements and medication order forms for prescribing physicians. Indeed, Gill et al.<sup>43</sup> reported that almost 38% of potentially inappropriate prescriptions were changed by the prescribing physician in response to follow-up letters suggesting safer alternatives. The Fleetwood Phase III study has successfully implemented prospective intervention for residents receiving a potentially inappropriate medication as well as identifying those at high risk for medication related problems.<sup>12</sup> Given the success of similar interventions, we believe that the incorporation of the "real-time" inappropriate drug alerts and prospective intervention using treatment algorithms will result in decreases in the use of these medications.

Pharmacists working within the long-term care setting must ensure that prescribing meets the federal standards as dictated by the Omnibus Budget Reconciliation Act regulations,<sup>17</sup> and this limits the time which can be spent on other aspects of pharmaceutical care.

At present, pharmacists are not paid for their clinical services and, as such, the pharmacist's role in optimizing pharmacotherapy in nursing home residents may be less than ideal. The Fleetwood Model will demand greater involvement of pharmacists in planning and delivering pharmaceutical care. Identification of residents on potentially inappropriate medications and prospectively intervening should maximize resources in

terms of the pharmacists' input and their time. It has been shown in the Veterans Affairs Medical Center system that a clinical pharmacist providing pharmaceutical care for elderly primary care patients can reduce inappropriate prescribing and possibly adverse drug effects without adversely affecting health-related quality of life.<sup>44</sup> We believe the Fleetwood Model will produce similar findings in the nursing home setting.

## CONCLUSION

Despite regulatory intervention, potentially inappropriate medication use is still prevalent in the nursing home setting. The implementation of evidence-based treatment algorithms may reduce the prevalence of potentially inappropriate medications used in nursing home settings. We believe that the treatment algorithms described here will be useful in the Fleetwood Phase III study. However, consensus-based statements identifying appropriate alternatives would lead to wider-scale dissemination and acceptance of these treatment algorithms and potentially help geriatric clinicians, researchers, and policy-makers in improving the quality of health care that the elderly receive. In summary, the Fleetwood Phase III study is using the treatment algorithms described. The next stage will involve integrating these algorithms with the other elements of the Fleetwood Model as part of the definitive evaluation of this comprehensive approach to pharmaceutical care.

**Authors' Note:** The following algorithms were developed before the most recent publication of the updated Beers criteria.<sup>4</sup>