**Section 390.APPENDIX C Guidelines for the Use of Various Drugs**

A. Long-Acting Benzodiazepine Drugs

Long-acting benzodiazepine drugs should not be used in residents unless an attempt with a shorter-acting drug (i.e., those listed under B. Benzodiazepine or Other Anxiolytic/Sedative Drugs, and under C. Drugs Used for Sleep Induction) has failed.

After an attempt with a shorter-acting benzodiazepine drug has failed, a long-acting benzodiazepine drug should be used only if:

1. Evidence exists that other possible reasons for the resident's distress have been considered and ruled out;

2. Its use results in maintenance or improvement in the resident's functional status;

3. Daily use is less than four continuous months unless an attempt at a gradual dose reduction is unsuccessful; and

4. Its use is less than, or equal to, the following listed total daily doses unless higher doses (as evidenced by the resident's response and/or the resident's clinical record) are necessary for the maintenance or improvement in the resident's functional status.

|  |  |  |
| --- | --- | --- |
| EXAMPLES OF LONG-ACTING BENZODIAZEPINES (not maximum doses) | | |
|  |  |  |
|  |  | Daily Oral |
| Generic | Brand | Dosage |
|  |  |  |
| Flurazepam | (Dalmane) | 15mg |
| Chlordiazepoxide | (Librium) | 20mg |
| Clorazepate | (Tranxene) | 15mg |
| Diazepam | (Valium) | 5mg |
| Clonazepam | (Klonopin) | 1.5mg |
| Quazepam | (Doral) | 7.5mg |
| Halazepam | (Paxipam) | 40mg |

NOTES:

When diazepam is used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia or seizure disorders), this Guideline does not apply.

When long-acting benzodiazepine drugs are being used to withdraw residents from short-acting benzodiazepine drugs, this Guideline does not apply.

When clonazepam is used in bi-polar disorders, management of tardive dyskinesia, nocturnal myoclonus or seizure disorders, this Guideline does not apply.

The daily doses listed under Long-Acting Benzodiazepines are doses (usually administered in divided doses) for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence to show why it was necessary for the maintenance or improvement in the resident's functional status.

For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is "clinically contraindicated."

B. Benzodiazepine or other Anxiolytic/Sedative Drugs

Use of the listed Anxiolytic/Sedative drugs for purposes other than sleep induction should only occur if:

1. Evidence exists that other possible reasons for the resident's distress have been considered and ruled out;

2. Use results in a maintenance or improvement in the resident's functional status;

3. Daily use (at any dose) is less than four continuous months unless an attempt at a gradual dose reduction is unsuccessful;

4. Use is for one of the following indications as defined by the Diagnostic and Statistical Manual of Mental Disorders; Fourth Edition (DSM-IV):

Generalized anxiety disorder;

Organic mental syndromes (now called dementia, delirium and amnestic and other "cognitive disorders" by DSM-IV) with associated agitated states which are quantitatively and objectively documented, which are persistent and not due to preventable reasons and which constitute sources of distress or dysfunction to the resident or represent a danger to the resident or others;

Panic disorder;

Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder (e.g., depression, adjustment disorder); and

5. Use is equal to or less than the following listed total daily doses, unless higher doses (as evidenced by the resident's response and/or the resident's clinical record) are necessary for the improvement or maintenance in the resident's functional status.

|  |  |  |
| --- | --- | --- |
| EXAPLES OF SHORT-ACTING BENZODIAZEPINES (not maximum doses) | | |
|  |  |  |
|  |  | Daily Oral |
| Generic | Brand | Dosage |
|  |  |  |
| Lorazepam | (Ativan) | 2mg |
| Oxazepam | (Serax) | 30mg |
| Alprazolam | (Xanax) | 0.75mg |

|  |  |  |
| --- | --- | --- |
| EXAMPLES OF OTHER ANXIOLYTIC AND SEDATIVE DRUGS | | |
|  |  |  |
|  |  | Daily Oral |
| Generic | Brand | Dosage |
|  |  |  |
| Diphenhydramine | (Benadryl) | 50mg |
| Hydroxyzine | (Atarax, Vistaril) | 50mg |
| Chloral Hydrate | (Many Brands) | 750mg |

NOTES:

This documentation is often referred to as "behavioral monitoring charts" and is necessary to assist in: (a) assessing whether the resident's behavioral symptom is in need of some form of intervention, (b) determining whether the behavioral symptom is transitory or permanent, (c) relating the behavioral symptom to other events in the resident's life in order to learn about potential causes (e.g., death in the family, not adhering to the resident's customary daily routine), (d) ruling out environmental causes such as excessive heat, noise, overcrowding, etc., (e) ruling out medical causes such as pain, constipation, fever, infection.

The daily doses listed under Short-Acting Benzodiazepines are doses (usually administered in divided doses) for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence to show why it was necessary for the maintenance or improvement in the resident's functional status.

For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that a gradual dose reduction is "clinically contraindicated."

Diphenhydramine, hydroxyzine and chloral hydrate are not necessarily drugs of choice for treatment of anxiety disorders. They are only listed here in the event of their potential use.

C. Drugs Used for Sleep Induction

Drugs used for sleep induction should only be used if:

1. Evidence exists that other possible reasons for insomnia (e.g., depression, pain, noise, light, caffeine) have been ruled out;

2. The use of a drug to induce sleep results in the maintenance or improvement of the resident's functional status;

3. Daily use of the drug is less than ten continuous days unless an attempt at a gradual dose reduction is unsuccessful;

4. The dose of the drug is equal to or less than the following listed doses unless higher doses (as evidenced by the resident's response and/or the resident's clinical record) are necessary for maintenance or improvement in the resident's functional status.

|  |  |  |
| --- | --- | --- |
| EXAMPLES OF HYPNOTIC DRUGS (not maximum doses) | | |
|  |  |  |
| Generic | Brand | Oral Dosage |
|  |  |  |
| Temazepam | (Restoril) | 7.5mg |
| Triazolam | (Halcion) | 0.125mg |
| Lorazepam | (Ativan) | 1mg |
| Oxazepam | (Serax) | 15mg |
| Alprazolam | (Xanax) | 0.25mg |
| Estazolam | (ProSom) | 0.5mg |
| Diphenhydramine | (Benadryl) | 25mg |
| Hydroxyzine | (Atarax, Vistaril) | 50mg |
| Chloral Hydrate | (Many Brands) | 500mg |
| Zolpiden | (Ambien) | 5mg |

NOTES:

Diminished sleep in the elderly is not necessarily pathological.

The doses listed are doses for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence to show why it was necessary for the maintenance or improvement in the resident's functional status.

Diphenhydramine, hydroxyzine, and chloral hydrate are not necessarily drugs of choice for sleep disorders. They are listed here only in the event of their potential use.

For drugs in this category, a gradual dose reduction should be attempted at least three times within six months before one can conclude that a gradual dose reduction is "clinically contraindicated."

D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs

The initiation of the following hypnotic/sedative/anxiolytic drugs should not occur in any dose for any resident. (See Notes for exceptions.) Residents currently using these drugs or residents admitted to the facility while using these drugs should receive gradual dose reductions as part of a plan to eliminate or modify the symptoms for which they are prescribed. A gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated. Newly admitted residents using these drugs may have a period of adjustment before a gradual dose reduction is attempted.

**(Caution: The rapid withdrawal of these drugs might result in severe physiological withdrawal symptoms.)**

|  |  |
| --- | --- |
| EXAMPLES OF BARBITURATES | |
|  |  |
| Generic | Brand |
|  |  |
| Amobarbital | (Amytal) |
| Amobarbital-Secobarbital | (Tuinal) |
| Butabarbital | (Butisol, others) |
| Pentobarbital | (Nembutal) |
| Secobarbital | (Seconal) |
| Phenobarbital | (Many Brands) |
| Barbiturates with other drugs | (e.g., Fiorinal) |

|  |  |
| --- | --- |
| EXAMPLES OF MISCELLANEOUS HYPNOTIC/SEDATIVE/ANXIOLYTICS | |
|  |  |
| Generic | Brand |
|  |  |
| Ethchlorvynol | (Placidyl) |
| Glutethimide | (Doriden) |
| Meprobamate | (Equinal, Miltown) |
| Methprylon | (Noludar) |
| Paraldehyde | (Many Brands) |

NOTES:

Any sedative drug is excepted from this Guideline when used as a single dose sedative for dental or medical procedures.

Phenobarbital is excepted from this Guideline when used in the treatment of seizure disorders.

When Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs are used outside these Guidelines, they may be unnecessary drugs as a result of inadequate indications for use.

E. Antipsychotic Drugs

The following examples of antipsychotic drugs should not be used in excess of the listed doses for residents with organic mental syndromes (now called dementia, delirium, and amnestic and other "cognitive disorders" by DSM-IV) unless higher doses (as evidenced by the resident's response or the resident's clinical record) are necessary to maintain or improve the resident's functional status.

|  |  |  |
| --- | --- | --- |
| EXAMPLES OF ANTIPSYCHOTIC DRUGS FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES (not maximum doses) | | |
|  |  |  |
| Generic | Brand | Daily Oral Dosage |
|  |  |  |
| Chlorpromazine | (Thorazine) | 75mg |
| Promazine | (Sparine) | 150mg |
| Triflupromazine | (Vesprin) | 20mg |
| Thioridazine | (Mellaril) | 75mg |
| Mesoridazine | (Serentil) | 25mg |
| Acetophenazine | (Tindal) | 20mg |
| Perpnenazine | (Trilafon) | 8mg |
| Fluphenazine | (Prolixin, Permitil) | 4mg |
| Trifluoperazine | (Stelazine) | 8mg |
| Chlorprothixene | (Taractan) | 75mg |
| Thiothixene | (Navane) | 7mg |
| Haloperidol | (Haldol) | 4mg |
| Molindone | (Moban) | 10mg |
| Loxapine | (Loxitane) | 10mg |
| Clozapine | (Clozaril) | 50mg |
| Prochlorperazine | (Compazine) | 10mg |
| Risperidone | (Resperdal) | 4mg |

NOTES:

The doses listed are daily doses (usually administered in divided doses) for residents with organic mental syndromes (now called dementia, delirium, and amnestic and other "cognitive disorders" by DSM-IV). The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence to show why it is necessary for the maintenance or improvement in the resident's functional status.

The "specific conditions" for use of antipsychotic drugs are listed under this Guideline under G.

The dose of prochlorperazine may be exceeded for short term (seven day) treatment of nausea and vomiting. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can also be treated with higher doses for longer periods of time.

When antipsychotic drugs are used outside these Guidelines, they may be deemed unnecessary drugs as a result of excessive doses.

F. Monitoring for Antipsychotic Drug Side Effects

The facility assures that residents who are undergoing antipsychotic drug therapy receive adequate monitoring for significant side effects of such therapy with emphasis on the following:

1. Tardive dyskinesia;

2. Postural (orthostatic) hypotension;

3. Cognitive/behavior impairment;

4. Akathisia; and

5. Parkinsonism.

When antipsychotic drugs are used without monitoring for these side effects, they may be unnecessary drugs because of inadequate monitoring.

G. Use of Antipsychotic Drugs

Antipsychotic drugs should not be used unless the clinical record documents that the resident has one or more of the following "specific conditions":

1. Schizophrenia;

2. Schizo-affective disorder;

3. Delusional disorder;

4. Psychotic mood disorders (including mania and depression with psychotic features);

5. Acute psychotic episodes;

6. Brief reactive psychosis;

7. Schizophreniform disorder;

8. Atypical psychosis;

9. Tourette's disorder;

10. Huntington's disease;

11. Organic mental syndromes (now called dementia, delirium, and amnestic and other "cognitive disorders" by DSM-IV) with associated psychotic and/or agitated behaviors:

Which have been quantitatively (number of episodes) and objectively (e.g., biting, kicking, scratching) documented. This documentation is necessary to assist in: (a) assessing whether the resident's behavioral symptom is in need of some form of intervention, (b) determining whether the behavioral symptom is transitory or permanent, (c) relating the behavioral symptom to other events in the resident's life in order to learn about potential causes (e.g., death in the family, not adhering to the resident's customary daily routine), (d) ruling out environmental causes such as excessive heat, noise, overcrowding, (e) ruling out medical causes such as pain, constipation, fever, infection;

Which are persistent;

Which are not caused by preventable reasons; and

Which are causing the resident to:

Present a danger to her/himself or to others,

Continuously cry, scream, yell, or pace if these specific behaviors cause an impairment in functional capacity, or

Experience psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as dangerous behaviors or as crying, screaming, yelling, or pacing but which cause the resident distress or impairment in functional capacity; or

12. Short term (seven days) symptomatic treatment of hiccups, nausea, vomiting or pruritus. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can be treated for longer periods of time.

Antipsychotics should not be used if one or more of the following is/are the only indication:

1. Wandering,

2. Poor self care,

3. Restlessness,

4. Impaired memory,

5. Anxiety,

6. Depression (without psychotic features),

7. Insomnia,

8. Unsociability,

9. Indifference to surroundings,

10. Fidgeting,

11. Nervousness,

12. Uncooperativeness, or

13. Agitated behaviors which do not represent danger to the resident or others.

H. Antipsychotic Drug Gradual Dose Reduction

Residents must, unless clinically contraindicated, have gradual dose reductions of the antipsychotic drug. The gradual dose reduction should be under close supervision. If the gradual dose reduction is causing an adverse effect on the resident and the gradual dose reduction is discontinued, documentation of this decision and the reasons for it should be included in the clinical record. Gradual dose reductions consist of tapering the resident's daily dose to determine if the resident's symptoms can be controlled by a lower dose or to determine if the dose can be eliminated altogether.

"Behavioral interventions" means modification of the resident's behavior or the resident's environment, including staff approaches to care, to the largest degree possible to accommodate the resident's behavioral symptoms.

"Clinically contraindicated" means that a resident need not undergo a "gradual dose reduction" or "behavioral intervention" if the resident has a "specific condition" (as listed in these Guidelines under G, 1-11) and has a history of recurrence of psychotic symptoms (e.g., delusions, hallucinations) which have been stabilized with a maintenance dose of an antipsychotic drug without incurring significant side effects (e.g., tardive dyskinesia). In residents with organic mental syndromes (now called dementia, delirium, and amnestic and other "cognitive disorders" by DSM-IV), "clinically contraindicated" means that a gradual dose reduction has been attempted twice in one year and that attempt resulted in the return of symptoms for which the drug was prescribed to a degree that a cessation in the gradual dose reduction, or a return to previous dose levels, was necessary. The resident's physician provides a justification why the continued use of the drug and the dose of the drug is clinically appropriate. This justification should include: (a) a diagnosis, but not simply a diagnostic label or code, but the description of symptoms, (b) a discussion of the differential psychiatric and medical diagnosis (e.g., why the resident's behavioral symptom is thought to be a result of a dementia with associated psychosis and/or agitated behaviors, and not the result of an unrecognized painful medical condition or a psychosocial or environmental stressor), (c) a description of the justification for the choice of a particular treatment, or treatments, and (d) a discussion of why the present dose is necessary to manage the symptoms of the resident. This information need not necessarily be in the physician's progress notes, but must be a part of the resident's clinical record.

I. Antidepressant Drugs

The facility is not required to use behavioral monitoring charts when antidepressant drugs are used. "Behavioral monitoring charts" include such records as quantitative evidence (number of episodes) and objective evidence (e.g., withdrawn behavior such as the resident staying in his/her room, refusal to speak, etc.) of patient behavior necessitating the use of the antidepressant drugs. The following is a list of commonly used antidepressant drugs:

|  |  |
| --- | --- |
| EXAMPLES OF ANTIDEPRESSANT DRUGS | |
|  |  |
| Generic | Brand |
|  |  |
| Amitriptyline | (Elavil) |
| Amoxapine | (Asendin) |
| Desipramine | (Norpramin, Pertofrane) |
| Doxepin | (Sinequan) |
| Imipramine | (Tofranil) |
| Maprotiline | (Ludiomil) |
| Nortriptyline | (Aventyl, Panelor) |
| Protriptyline | (Vivactil) |
| Trimipramine | (Surmontil) |
| Fluoxetine | (Prozac) |
| Sertaline | (Zoloft) |
| Trazodone | (Desyrel) |
| Clomipramine | (Anafranil) |
| Paroxetine | (Paxil) |
| Bupropion | (Wellbutrin) |
| Isocarboxazid | (Marplan) |
| Phenelzine | (Nardil) |
| Tranylcypromine | (Parnate) |
| Venlafaxine | (Effexor) |
| Nefazadone | (Serzone) |
| Fluvoxamine | (Luvox) |

J. Exceptions to These Guidelines

The facility shall have the opportunity to provide a rationale for the use of drugs prescribed outside these Guidelines. The facility may not justify the use of a drug prescribed outside these Guidelines solely on the basis of "the doctor ordered it." The rationale must be based on sound risk-benefit analysis of the resident's symptoms and potential adverse effects of the drug.

The unnecessary drug criterion of "adequate indications for use" does not simply mean that the physician's order must include a reason for using the drug (although such order writing is encouraged). It means that the resident lacks a valid clinical reason for use of the drug as evidenced by the evaluation of some, but not necessarily all, of the following: resident assessment, plan of care, reports of significant change, progress notes, laboratory reports, professional consults, drug orders, observation and interview of the resident, and other information.

In determining whether an antipsychotic drug is without a "specific condition" or that "gradual dose reduction and behavioral interventions" have not been performed, the facility shall justify why using the drug outside these Guidelines is in the best interest of the resident.

Examples of evidence that would support a justification of why a drug is being used outside these Guidelines but in the best interests of the resident may include, but are not limited to:

1. A physician's note indicating, for example, that the dosage, duration, indication, and monitoring are clinically appropriate, and the reasons why they are clinically appropriate; this note should demonstrate that the physician has carefully considered the risk/benefit to the resident in using drugs outside these Guidelines;

2. A medical or psychiatric consultation or evaluation (e.g., Geriatric Depression Scale) that confirms the physician's judgment that use of a drug outside these Guidelines is in the best interest of the resident;

3. Physician, nursing, or other health professional documentation indicating that the resident is being monitored for adverse consequences or complications of the drug therapy;

4. Documentation confirming that previous attempts at dosage reduction have been unsuccessful;

5. Documentation (such as MDS documentation) showing resident's subjective or objective improvement, or maintenance of function while taking the medication;

6. Documentation showing that a resident's decline or deterioration is evaluated by the interdisciplinary team to determine whether a particular drug, or a particular dose, or duration of therapy, may be the cause;

7. Documentation showing why the resident's age, weight, or other factors would require a unique drug dose or drug duration, indication, monitoring; and

8. Other evidence which may be appropriate.

(Source: Added at 20 Ill. Reg. 12101, effective September 10, 1996)