



***Division of Developmental Disabilities Services
Community Services/ Adult Special Populations***

**Health Care Services Protocol #1:
'Training Module' and 'Practical Protocol for Use'
Of Diazepam Rectal Gel (Diastat)**

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Rational

The purpose of this health care services protocol is to maximize the safe and appropriate use of diazepam rectal gel (Diastat) prescribed by community physicians to individuals receiving Community Services (CS) and Adult Special Populations (ASP) residential and day program services. Also, it is both a training and informational module about the use of Diastat in CS and ASP for (1) prescribers, (2) nurses, (3) provider agencies administrators, (4) 'shared living' providers, (5) direct care staff caregivers, (6) trainers, and (7) individuals and families. Diastat is a medication designed to stop prolonged seizures and clusters of increased seizure activity. It comes in a pre-filled, unit-dose, non-sterile rectal delivery system. Using Diastat is considered to be faster and easier than going to the emergency room when used as described in the package insert. It has been shown to begin working within 5 to 15 minutes. It works much quicker than oral medication and is much easier to give than intravenous diazepam.

Diastat is intended and approved for rectal administration by "non-health professionals" (term used in package insert) in the management of selected, refractory patients with epilepsy, on stable regimens of anti-epileptic drugs who require intermittent use of diazepam to control bouts of increased seizure activity. The product labeling for Diastat (http://www.diastat.com/HTML-INF/pdf/64016_DiaStat.pdf) addresses the issue of "non-health professional caregiver" administration. Diastat is not recommended for chronic, daily use as an anticonvulsant because of the potential for the development of tolerance to diazepam. In clinical trials, the most frequent adverse event reported was somnolence (drowsiness) (23%). Less frequent adverse events were dizziness, headache, pain, abdominal pain, nervousness, vasodilation (dilatation of small arteries), diarrhea, ataxia (unsteady gait or muscular uncoordination), euphoria, incoordination, asthma, rhinitis (itchy, runny nose), and rash (2%-5%).

This protocol only pertains to the Diastat AcuDial diazepam rectal gel preparation. Any other Diastat preparation requires special attention and should

be discussed with the Community Services Nursing Program Administrator. For the purposes of this protocol the term 'community nurse' is meant to reflect the assigned nurse for the individual prescribed Diastat, whether that nurse is a DDS Community Services Nurse or a contracted, provider agency nurse.

The Prescription Process

"A decision to prescribe Diastat involves more than the diagnosis and selection of the correct dose for the patient. First, the prescriber must be convinced from historical reports and/or personal observations that the patient exhibits the characteristic identifiable seizure cluster that can be distinguished from the patient's usual seizure activity by the caregiver who will be responsible for administering Diastat. Second, because Diastat is intended for adjunctive use, the prescriber must ensure that the patient is receiving an optimal regimen of standard anti-epileptic drug treatment and is, nevertheless, continuing to experience these characteristic episodes. Third, because a 'non-health professional' will be obliged to identify episodes suitable for treatment, make the decision to administer treatment upon that identification, administer the drug, monitor the patient, and assess the adequacy of the response to treatment, a major component of the prescribing process involves the necessary instruction of this individual. Fourth, the prescriber and caregiver must have a common understanding of what is and is not an episode of seizures that is appropriate for treatment, the timing of administration in relation to the onset of the episode, the mechanics of administering the drug, how and what to observe following administration, and what would constitute an outcome requiring immediate and direct medical attention." (Product label)

"Diastat should only be administered by caregivers who, in the opinion of the prescribing physician: (1) are able to distinguish the distinct cluster of seizures (and/or the events presumed to herald their onset) from the patient's ordinary seizure activity, (2) have been instructed and judged to be competent to administer the treatment rectally, (3) understand explicitly which seizure manifestations may or may not be treated with Diastat, and (4) are able to monitor the clinical response and recognize when that response is such that immediate professional medical evaluation is required." (Product label: emboldened font)

Since the proper use of Diastat depends, in large measure, on the performance of a "non-health professional", it is necessary to have a protocol that ensures such individuals have the support and training required to carry out this task. This is especially critical because individuals receiving residential and day program services from CS and ASP have numerous "non-health professional caregivers" (from here on to be referred to as "direct care staff caregiver"), caring for them. Any of them may be called upon to give this medication if circumstances require it. The prescriber's role, as stated in the product label, is

“to take all reasonable steps to ensure that caregivers fully understand their role and obligations vis-à-vis the administration of Diastat to individuals in their care.”

No prescriber will have the opportunity to individually instruct all of the “non-health professional caregivers” for any one individual. This underscores the need for this protocol. One requirement is to expect that prescribers complete the Diastat Order Form (Appendix A) upon prescribing Diastat. It is to be reviewed at each appointment and upon the request of a caregiver or health professional.

Note that this protocol was presented to the Delaware Board of Nursing in the fall of 2004. They considered the use of this medication, in the manner expressed above, as “assistance with medications” and, as such, it is not a delegated nursing duty according to the Nurse Practice Act rules and regulations. During the same time frame, the protocol was also presented to the Board of Medical Practice and several of its members gave helpful critical commentary.

Education and Participation of the Consumer

It is the expectation of this protocol that all parties (the prescriber, caregivers, behavioral service professionals and community nurses) will involve the individual in all aspects of decision-making relative to Diastat to the extent that that person’s cognitive capacity will allow. Policies and practices regarding informed consent should be adhered to. Also, legal guardians or alternative/ surrogate decision-makers should be involved in this process and their participation should be documented on the Diastat Order Form. The opportunity for questions to be asked by the individual or their representative should be granted. It is the responsibility of the community nurse to make sure that a copy of the module is given to the agent for informed consent. Importantly, there needs to be an appreciation by all caregivers that an individual’s privacy and dignity need to be respected, to the greatest extent possible, during the administration of Diastat. This issue will be addressed as part of the training of caregivers.

Training of Direct-Care Staff Caregivers and the Role of the Community Nurse

1. Direct-care staff caregivers expected to administer Diastat will receive instruction on the administration of Diastat as part of their initial “Assist with Medication” curriculum. This training will also be part of the yearly recertification process. The training includes a didactic instruction, a video presentation, and a review of a “How to Administer” Instruction Sheet (http://www.diastat.com/HTML-INF/Epilepsy_Resources/Epilepsy_Printable_Forms_B.htm) produced by the manufacturers of Diastat. There is a Performance Checklist for Diastat Administration (Appendix B) that is part of the training evaluation. Competency is exhibited through recall of

information and demonstration in the areas of the Performance Checklist for Diastat Administration.

2. **Transportation staff (attendant chauffeurs) are not trained in “assisting with medication” and so, administration of Diastat cannot be performed during transportation time. Drivers are instructed to call 911 if a refractory seizure occurs.**
3. All direct-care staff caregivers accompanying individuals to the prescriber’s office are required to ask to review the completed Diastat Order Form with the prescriber. It is the responsibility of the program supervisor(s) to assure that all responsible direct-care staff caregivers review this document and have the opportunity to ask questions. The Diastat Order Form should be reviewed at each subsequent appointment. A copy of that document should be faxed to the community nurse on the same day that the document is produced. Also, on that day, the community nurse, or nurse supervisor, should be verbally informed that such a document has been generated.
4. The community nurse, or one of her nursing colleagues/supervisors, will perform an on-site training for each involved program within two days of the date of the prescription (or sooner if requested by the program supervisor). Also, the nurse will develop an ‘Individual Diastat Protocol’ (**Appendix C**). S/he, or nurse supervisor, will be available for further questions and technical assistance on an as-needed basis. Documentation that includes information on (1) actual episodes in which Diastat is given and (2) related E.R. visits will be part of regular nursing documentation. At the time of the on-site training, the community nurse will review and verify the Diastat dosages and readiness of the AcuDial syringes.

The Responsibility of Provider Agencies

Besides that which is cited in the above sections, the responsibilities of provider agencies are:

1. To assure that all direct-care staff caregivers and program supervisors caring for an individual prescribed Diastat in one of their programs have received the required training outlined in number 1 of the above section.
2. To assure that program supervisors will verbally inform, in a timely manner, the prescriber, the community nurse, & other provider agencies that a dose of Diastat has been given to an individual. Also, a copy of the Diastat Communication Form (**Appendix D**) should be faxed to the above parties.

3. To monitor adherence to the instructions that are written on the Diastat Order Form and the Individualized Diastat Protocol.
4. For each episode of Diastat usage, a thorough event note should be documented in the chart, which includes a description of the seizure, length of seizure, time and dose of Diastat given, & the response of the individual to the medication & side effects noted.
5. A last but very important responsibility of the supervising house manager is to check the AcuDial syringes when they come from the pharmacy:
 - (1) Remove the syringes from the case.
 - (2) Confirm the dose is visible in the dose display window and is the dose that is written by the prescriber on the Diastat Order Form. Do this for each of the syringes.
 - (3) Confirm that the green "READY" band is visible. Do this for each of the syringes.
 - (4) Return both syringes to the case.
 - (5) The community nurse will review these items when s/he performs her on-site training session.

Placement of Forms

Appendix A: Diastat Order Form

The original form is to be placed in the 'Specialist Section: Neurology'. A current copy of the form can be placed in the MAR Book to facilitate quick access.

Appendix B: Performance Checklist for Diastat Administration

The placement and maintenance of these forms will be determined by T.A.P.D.

Appendix C: 'Individual Diastat Protocol'

The original form is to be placed in the 'Nursing ELP'. A current copy of the form can be placed in the MAR Book to facilitate quick access.

Appendix D: Diastat Communication Form

The original form is to be placed in the 'Flowsheet Section' along with the MAR flowsheets. A current copy of the form can be placed in the MAR Book to facilitate quick access.

References:

- (1) Diastat Package Insert, Xcel Pharmaceuticals, Inc., San Diego, CA 92122
- (2) Educational Instruction Sheets, Xcel Pharmaceuticals, Inc., San Diego, CA 92122
- (3) Diastat Protocol, Sharon Onxx, Director of Health Services, Massachusetts DMR, August 2004.
- (4) *Risky Business: A Discussion of State Strategies for Managing and Responding to Risk and Liability*, NADDDDS Teleconference Series, July 22, 2004.
- (5) Notes from discussion with Dr. Andrew Eddy, Dir. of Health Services, Ohio DMR, August 2004.
- (6) Notes from discussion with Delaware Medical Practice Board, September 7, 2004.



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Diastat Order Form

- *Form can only be completed by a physician; preferably a neurologist.**
- *Form must be reviewed at each appointment & rewritten within a 1- year period.**

Name of Patient: _____ **Date:** _____

Seizure Diagnosis: _____

DOB: _____ **MCI #:** _____ **Weight:** _____

Usual Seizure Type/Seizure Clusters:

Diastat Medical Order: (should be the same as is on the prescription)

Diastat should NOT be given when:

After treatment with Diastat you must:

1. Stay with the person for at least 4 hours;
2. Make note and document the following:
 - a. Changes in resting breathing rate
 - b. Changes in skin color
 - c. Drowsiness that extends beyond the 4 hour period of observation
3. Other things to monitor include: _____

Call my office at telephone number (302) _____ - _____ if any of the following occur:

1. Seizure frequency or severity is different from other episode;
2. If you have given a dose of Diastat;
3. Other reasons to call: _____

Call 911 if any of the following happens after you have given a dose of Diastat:

1. Seizures continue 15 minutes after giving Diastat.
2. The person has needed Diastat twice within the last 24 hours.
3. The person has injured themselves or appears to be having unusual or serious problems.
4. The seizure behavior is different from other episodes.
5. You are alarmed by the skin color (blue, red, or pale) or the breathing pattern of the person.
6. You are alarmed by the frequency or severity of the seizure(s).

Physician's Sign. / Date

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Sign. Of Person Giving Informed Consent / Date



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Performance Checklist for Diastat Administration

Employee Name: _____	Pass	Fail	Comments
Able to state what Diastat is and when it is used.			
<ol style="list-style-type: none"> 1. Compares the doctor's written orders with the MAR and the prescription label at the beginning of the shift. 2. Checks the expiration date and if within one week of expiration, ensures that new supply has been ordered. 			
Can state what steps he/she would take if individual has a seizure.			
<p>After stating what conditions the individual would require the use of Diastat, is able to demonstrate the following steps:</p> <ol style="list-style-type: none"> 1. Compares the prescription label with the medication sheet and brings Diastat to the individual. 2. With individual in proper position (pants down, on side, with upper leg bent forward, facing employee), opens Diastat pack and removes one delivery system and packet of lubricating jelly. 3. With thumb, removes the protective covering from the system (making sure that the seal pin is removed) and puts tip into opened packet of lubricating jelly. 4. Properly gives medication; slowly counting to three while pushing plunger in and when removing the tip from rectum. Holds buttocks together for another three seconds. 			
<ol style="list-style-type: none"> 1. Able to state when dose (if at all) may be repeated. 2. Able to state what she/he would do if Diastat is not effective. 3. Able to state the possible side effects of Diastat. 4. Able to state what kind of monitoring the individual needs after receiving a dose Diastat. 5. Able to state what to do if a second dose of Diastat is given 			
<p>After seizures are controlled (or ER staff have arrived) and the individual is cared for:</p> <ol style="list-style-type: none"> 1. Compares label to MAR when documenting dose. 2. Documents use in count book. 3. Documents in seizure record, progress notes, and communication book. 4. Informs incoming staff, day/home staff, prescriber, and community nurse of the use of Diastat. 5. Properly disposes of Diastat materials. 			

This employee has demonstrated [] successful [] unsuccessful completion of the above steps.

Signature of Employee

Signature of Examiner

Date



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Individual Diastat Protocol: Example

Individual's Name/ MCI Number: _____ **Date:** _____

Refer to "Diastat AcuDial Administration Instructions"

This form should be attached by the community nurse to this Individualized Protocol.

It can be found on the internet at, as noted on page one:

[www.diastat.com/HTML-INF/Epilepsy Resources/Epilepsy Printable Forms B.htm](http://www.diastat.com/HTML-INF/Epilepsy_Resources/Epilepsy_Printable_Forms_B.htm)

1. When _____ has a seizure episode which meets the requirement for Diastat as stated on the Diastat Order Sheet: Remain calm, protect _____ from falls by guiding her/him to a lying position, turn him/her on their side to avoid aspiration, and continue to observe them.
2. Get _____'s Diastat and return. While observing _____, open the box and remove one of the Diastat "AcuDial" delivery system (looks like a syringe), and a packet of lubricating jelly.
3. With thumb, remove the protective cover from the syringe (**make sure Seal Pin is removed with the cap**). Tear open the packet of lubricating jelly and put the tip of the syringe into the jelly.
4. Turn _____ on side facing you. Bend their upper leg to expose the rectum (pants will need to be pulled down to expose rectum). With _____ on her side facing you and _____'s upper leg bend forward, separate _____'s buttock's to expose his/her rectum.
5. Do your best to have other people that you may be with to provide for _____'s privacy (such as using clothes or sheet items as area drapes) but realize that your main concern is to fully and properly expose _____'s buttock for the proper insertion of the syringe and delivery of the medication.
6. Gently insert the syringe tip into the rectum with the rim of the syringe snug against the rectum.

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7. Slowly count to three while gently pushing the plunger until it stops, and then slowly count to three before slowly removing the tip from the rectum. Then hold the buttocks together for another three seconds to prevent leaking. Slow, gentle movements will help the medicine stay in the rectum and hopefully prevent a reflex bowel movement.
8. **If seizure activity continues for 15 minutes after the dose is given, as stated on the Diastat Order Sheet, then call 911 and accompany _____ to the ER.**
9. If the seizures stop within ____ minutes, then continue to observe _____ closely for at least the next four hours. **Someone should be in the same room as _____ and be able to see _____'s face at all times).** Only if _____ is fully alert and awake, can he/she resume usual activities.
10. Count his/her respirations every 15 minutes for the next four hours. When at rest and not having seizures _____ usually takes 12 to 18 breaths per minute. Call 911 if _____'s breathing is slower than 8 breaths per minute or faster than 32 breaths per minute; _____'s skin, lips, or nail beds turn bluish/darker or a pale color; or _____ shows any other signs of severe respiratory distress such as wheezing or labored breathing. Call the community nurse, your supervisor, and the prescriber's office if _____ is not fully alert and awake after four hours.
11. Watch for sleepiness, dizziness, headache, abdominal discomfort, rash, facial flushing, diarrhea, or nasal congestion. If any of these occurs call your supervisor, the community nurse, and the prescriber's office.
12. Document in the communication book, MAR, seizure record, and progress notes that Diastat was given. Describe the seizure activity, including time and length. Also note whether Diastat was effective, how long it took, and any side effects.
13. Inform oncoming staff of _____'s condition and the time of Diastat administration. House staff should inform day program staff or day program staff should inform house staff, whichever the case may be, on the day that Diastat is given in order to prevent _____ from receiving more than the allowable number of doses. Supervisors should make certain that this communication takes place. See Appendix D. Transportation of _____ on that day will need to be evaluated by the supervisors of each program, with good communication and adequate supervision provided to assure safe transport of _____.

R.N.'s Signature

Date

Other considerations; besides instructions written on the Diastat Order Sheet:

1. As always, if _____'s seizures appear to be different from her/his usual ones or you observe breathing problems, change in color (blueness/ darker color), or other unusual or serious problems (such as head trauma), call 911 and accompany him/her to the ER.
2. **If _____ requires a second dose of Diastat within a twenty-four hour period, then call 911 and accompany _____ to the ER.**
3. _____ should not be left alone in his/her residence without a staff member who has been trained and signed off on the administration of Diastat.
4. Diastat should not be used more than once in 5 days or more than 5 times in one month. Please notify the community nurse if this is the case.
5. Avoid storing Diastat in extreme cold or hot places.
6. Diastat needs to be securely stored and kept under lock and key in the home residence and day program. If the individual is in the community it should be carried in a secure fashion.
7. Disposal Instructions for Diastat AcuDial:
 - a. Pull on plunger until it is completely removed from the syringe body.
 - b. Point tip over sink or toilet.
 - c. Replace plunger into syringe body, gently pushing plunger until it stops.
 - d. Flush toilet or rinse sink with water until gel is no longer visible.
 - e. Discard all used materials in the garbage can securely.
 - f. Do not reuse.
 - g. Discard in a safe and secure place away from children and other individuals who may try to go into the garbage.



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Diastat Communication Form

Individual's Name: _____

MCI Number: _____

Date: _____

**This Diastat Communication Form is to inform you that on _____,
at _____ am/pm, _____ was given _____ mg. of Diastat.**

Name of Day or Residential Staff filling out form: _____

Signature of Day or Residential Staff filling out form: _____

✚ Name of Day or Residential Staff person receiving form:

✚ Name of Community Nurse receiving form:

✚ Name of Prescriber/ Physician receiving form:
