STANDARDIZED PROCEDURE
INTRATHECAL ADMINISTRATION OF NEUROTHERAPEUTIC AGENT VIA LUMBAR PUNCTURE (Adult)

These procedures are intended to describe procedures performed by Nurse Practitioners and/or Certified Nurse Midwives (depending on the clinical privileges granted to the individual practitioner) at UC San Diego Health.

I. Definition

The administration of neurotherapeutics via lumbar puncture into cerebrospinal fluid (CSF) for treatment of previously diagnosed nervous system disease. The procedure is also used for withdrawal of CSF for possible laboratory analysis and/or to check patency of system prior to administration of drug.

II. Background Information

A. Setting:
The setting (inpatient vs outpatient) and population (adults) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form.

B. Supervision:
The necessity of this procedure will be determined by the Advanced Health Practitioner in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the Advanced Health Practitioner.

Direct supervision will not be necessary once competency is determined, as provided for in the procedure. The Advanced Health Practitioner will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

C. Indications:

1. Patients with diagnosis of specific neurological disease treated by corresponding specific neurotherapeutic agent (eg. Spinraza for spinal muscular atrophy).

D. Precautions/Contraindications:

1. Thrombocytopenia (platelet count less than 50,000)
2. Evidence of increased intracranial pressure: Increased blood pressure with widened pulse pressure, papilledema, or significant decrease in the level of consciousness until imaging studies have ruled out mass effect.
3. New focal neurological findings and/or lesions, or imaging studies revealing significant mass effect.
4. Patients with coagulation defects or those receiving anticoagulant therapy.
5. Cutaneous infection at the site of procedure.
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6. Use caution with patients with a history of low back pain, lower extremity neuralgia or sciatica.
7. Patients with prior back surgery will be evaluated by the Neurosurgical Service prior to the procedure and may require they complete the procedure.

II. Materials
1. Standard LP kit
2. Atraumatic spinal needle
3. Chlorhexadine or iodine
4. Sterile gloves, sterile gown, hat, and mask
5. Neurotherapeutic agent to be prepared by UCSD Pharmacy according to manufacturer instructions in preparation for intrathecal delivery.

III. Procedure
A. Pre-treatment evaluation

1. Subjective
   a. History of pancytopenia, anticoagulation or aspirin use, renal insufficiency, disseminated intravascular coagulation, liver dysfunction, seizures; cerebral bleeding, head trauma or back surgery should be elicited.
   b. Review of systems: Headache, confusion, altered mental status, nuchal rigidity, fever, bleeding, lower extremity or back pain, difficulty with elimination or ambulation.

2. Patient Evaluation
   a. General appearances, vital signs, fever.
   b. Complete a focused neurological and mental status examination. Assess for focal neurologic findings. Evaluate for evidence of increased intracranial pressure: high blood pressure, widening pulse pressure, papilledema, and decreased level of consciousness. Evaluate for evidence of local infection or metabolic abnormalities.

3. Diagnostic
   a. Review for any previous lumbar puncture (MRI, CT results, if applicable).
   b. Diagnostics: CBC with platelets, coagulation factors (PT/PTT), cystatin C obtained on previous injection or prior to first injection.

B. Patient Preparation
1. After providing the purpose, risks and benefits, and steps of the procedure, obtain informed consent from the patient, family or appropriate legal designee.
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2. Perform the time out and document it in the patient record.

3. The most important step is positioning the patient. The lateral decubitus position may be used; firm bed, head on pillow, head flexed with chin on the chest, legs maximally flexed toward the head. Alternatively, the patient may be sitting, flexed forward and supported by stable table or assistant.

C. Perform Procedure
1. Identify interspaces and mark puncture site at the L4-5 interspaces in a perpendicular line from the iliac crest. The L3-4 interspace above this level may also be used.

2. Don hat, mask, sterile gown, and sterile gloves. Set up prepared LP tray.

3. Using sponge applicator provided in LP tray, prepare the back with Chlorhexadine or iodine solution, beginning at the site marked for the needle puncture and working outward. Repeat twice.

4. Drape the patient

5. Recheck the landmarks

6. Infiltrate the skin and subcutaneous tissue with preservative free 1% lidocaine with a 22-25-gauge needle.

7. Insert the introducer of the atraumatic spinal needle into the midline of the interspace with bevel up. Then, insert the atraumatic spinal needle into the introducer. Direct the needle on a 10-degree angle toward the umbilicus (horizontal axis).

8. Advance the needle slowly, removing the stylet every 2-3 millimeters to check for CSF flow. If the patient complains of nerve root pain, do not advance the needle. Withdraw 2 millimeters, remove stylet and check for CSF. If none, then replace the stylet and remove. Remove the needle to subcutaneous tissue, change angle and continue. If repeated bony resistance is noted, discard the needle and replace it. If blood is returned, watch for clearing of fluid; if no clearing, replace the stylet, remove the needle and notify the attending MD or obtain help from Anesthesia colleagues.

9. Once CSF flow is established, rotate the needle 90 degrees counter-clock wise (bevel in transverse plane) for patients in the lateral decubitus position. If the patient is in the sitting position no adjustment is needed. (Needle should always enter with the bevel in the sagittal plane and be rotated to the axial plane, regardless of patient position)

10. Remove a corresponding amount of CSF to neurotherapeutic drug volume or as directed by specific neurotherapeutic agent (for Spinraza, remove 5ml of CSF).
11. Replace stylet while getting neurotherapeutic agent.

12. Assistant to remove Spinraza from packaging without touching top of bottle once CSF space is reached. Assistant to hold bottle on top of table; or follow manufacturer instructions for neurotherapeutic agent administration.

13. Withdraw all the fluid/medication from the bottle using the blunt-end needle and sterile 10ml syringe, slanting bottle on edge if necessary, to withdraw all fluid. Assistant to visually inspect bottle to ensure all fluid was removed. Remove blunt end needle from syringe.

14. Attach syringe with neurotherapeutic agent to atraumatic needle and administer slowly over 1-3 minutes.

15. Replace stylet, turn needle 90-degrees clockwise (sagittal plane) and remove needle.

16. Send CSF samples to the lab as indicated (CSF to be discarded for Spinraza).

D. Post-procedure
1. Cleanse procedure area of povidone iodine solution and place dry sterile dressing or bandage.
2. Advise patient to lie prone for 1 hour and to increase oral fluids over the next 12-24 hours.
3. Assess patient for any adverse reactions to procedure.
4. Label CSF specimen tubes and send to lab if indicated.
5. Instruct patient to observe LP site for any signs of bleeding or infection.
6. Provide post-procedural analgesics as needed.
7. Patient to have CBC, coagulation factors, Cystatin C obtain via phlebotomy prior to discharge (can be done either pre or post procedure) or labs required for specific therapeutic agent.

E. Follow-up treatment
The patient to follow up with treating attending physician. The Advanced Health Practitioner will notify supervising physician if prior labs are markedly abnormal.

F. Termination of treatment
1. Severe pain which persists
2. Failure to access the CSF space after three attempts and Anesthesia colleague fails.

IV. Documentation
A. Documentation is in the electronic medical record
1. Documentation of the pretreatment evaluation and any abnormal physical findings.
2. Record the time out, indication for the procedure, procedure, LP site, patient position, type and size of needle used, EBL, the outcome, amount of CSF withdrawn, specimen sent
to lab, how the patient tolerated the procedure, medications (drug, dose, route, & time) given, complications, and the plan in the note, as well as any teaching and discharge instructions.

B. If abnormal or unexpected findings are encountered, consider further evaluation or consulting with supervising physician as needed.

VI. Competency Assessment

B. Initial Competence

1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.

2. The Advanced Health Practitioner will demonstrate knowledge of the following:
   a. Medical indication and contraindications of lumbar puncture.
   b. Risks and benefits of the procedure
   c. Related anatomy and physiology
   d. Consent process (if applicable)
   e. Steps in performing the procedure
   f. Documentation of the procedure
   g. Ability to interpret results and implications in management.

3. Advanced Health Practitioner will observe the supervising physician perform each procedure three times and perform the procedure three times under direct supervision.

4. Supervising physician will document Advanced Health Practitioner’s competency prior to performing procedure without supervision.

5. The Advanced Health Practitioner will ensure the completion of competency sign off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

B. Continued proficiency

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.

2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioner must perform this procedure at least three times per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.

3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.