STANDARDIZED PROCEDURE
INTRATHECAL ADMINISTRATION OF NEUROTHERAPEUTICS VIA RESERVOIR

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 reservoir (eg. Ommaya Reservoir or port) 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 a surgically implanted reservoir (eg. Ommaya reservoir or port) and diagnosis of specific neurological disease treated by corresponding specific neurotherapeutic agent (eg. Spinraza for spinal muscular atrophy).

D. Precautions/Contraindications:
1. Evidence of increased intracranial pressure: increased blood pressure with widening pulse pressure, papilledema, bulging reservoir or significant decrease in the level of consciousness until imaging studies have ruled out mass effect.
2. New focal neurological findings and/or lesions or imaging studies with
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significant mass effect.

3. Cutaneous infection at the site of puncture.

III. Materials

Neurotherapeutic agent to be prepared by UCSD Pharmacy according to manufacturer instructions in preparation for intrathecal delivery. Eg. 5.1ml of Spinraza will be thawed according to manufacturer instructions, in original packaging, and delivered to bedside. 10 ml preservative-free normal saline in syringe, Sterile 10ml syringe, sterile long blunt end needle, Medtronic catheter access port kit, sterile gloves, povidone iodine solution.

IV. Intrathecal Neurotherapeutics via Reservoir Procedure

A. Pre-treatment evaluation:

1. Subjective
   a. History
      i. A previous history of pancytopenia, renal insufficiency, liver dysfunction, seizures, cerebral bleeding, head trauma should be elicited.

2. Signs and Symptoms
   a. Reservoir is intact and no evidence of any erythema or swelling.
   b. None of the following symptoms/signs are present at the time of the procedure: headache, confusion, altered mental status, nuchal rigidity, fever, new lower extremity weakness, back pain, difficulty with bowel/bladder elimination. If any of these symptoms/signs are present, further evaluation is necessary.

3. Objective
   a. Patient Evaluation
      i. General appearance, vital signs, with evaluation for fever.
      ii. Focused neurologic and mental status examination.
      iii. Assess for new focal neurologic findings. Evaluate for evidence of increased intracranial pressure: high blood pressure, widening pulse pressure, papilledema, decreased level of consciousness, and bulging of reservoir. Evaluate for evidence of localized infection or metabolic abnormalities.
b. Diagnostics: CBC with platelets, coagulation factors (PT/PTT), cystatin C obtained on previous injection or prior to first injection.

B. Procedure:

1. After providing the purpose, risks and benefits, and steps of the procedure obtain informed consent from the patient or appropriate legal designee if not obtained in the past 6 months.

2. Neurotherapeutic agent to be given from pharmacy. Neurotherapeutic agent to be prepared by pharmacy according to manufacturer instructions.

3. Assemble supplies.

4. Check reservoir site and feel boarders.

5. Set up the Port access kit.

6. Don sterile gloves, mask.

7. Scrub skin over reservoir vigorously three times with povidone iodine solution – allow to dry 2 minutes.

8. Drape the patient.

9. Use the 25 gauge non-coring needle attached to extension tube and clamp from the Port Access Kit and inserted directly into reservoir at a perpendicular angle to skin, and a volume of cerebrospinal fluid equal to chemotherapy drug volume (usually 2 – 6 ml) is removed. Withdraw CSF slowly over approximately 1 minute and then clamp extension tubing.

10. Assistant to remove Spinraza from packaging without touching top of bottle once reservoir patency is confirmed and hold bottle on top of table; or follow manufacturer instructions for neurotherapeutic agent administration.

11. Withdraw all the fluid/medication from the bottle using the blunt-end needle and sterile 10cc 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 and attach filter from Port Access Kit to syringe containing neurotherapeutic agent.

12. Unclamp extension tubing. Attach filter/syringe with neurotherapeutic agent to extension tubing and inject agent over approximately 1-3 minutes.

13. Remove filter/syringe from extension tubing. Attach syringe containing preservative free normal saline and flush needle and extension tubing with approximately 6 ml preservative free saline.

14. Remove needle and cleanse skin with saline and apply spot bandage to site.

15. CSF analysis as dictated by neurotherapeutic agent protocol. For Spinraza,
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discard CSF.

C. Post-Procedure:
   1. Assess patient for possible side-effects.
   2. Patient to have CBC, coagulation factors, Cystatin C or labs required for specific therapeutic agent via phlebotomy prior to discharge (can be done either pre or post procedure).
   3. Document pretreatment evaluation, informed consent, timeout, procedure, including type and size of needle, patient response, characteristics of CSF, neurotherapeutic drug administered, amount of CSF withdrawn, and required tests ordered on specimens, patient follow-up instructions, as well as any complications.

D. 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.

V. Documentation:

A. Documentation is in the electronic medical record
   1. Documentation of the pretreatment evaluation and any new abnormal physical findings.
   2. Record the time out, indication for the procedure, procedure, EBL, the outcome, 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:

A. 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 intrathecal neurotherapeutic agent
      b. Risks and benefits of the procedure
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- Related anatomy and physiology
- Consent process (if applicable)
- Steps in performing the procedure
- Documentation of the procedure
- Ability to interpret results and implications in management.

3. The Advanced Health Practitioner will observe this procedure at least three times in its entirety.

4. The Advanced Health Practitioner will perform three treatments/procedures under the direct observation of the supervising physician and such additional procedures as may be necessary to verify clinical competence.

5. The Advanced Health Practitioner will ensure the completion of competency sign off documents and send them directly to the medical staff office.

6. 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.