Alberta Aids to Daily Living

Bulletin #107

Prosthetics and Orthotics Validation Certificate
Question and Answer Session

1. Question/Comment	What is the purpose of prosthetic and orthotic (P&O) vendors providing a signed and completed copy of the validation certificate to clients?
Current Policy	**<u>Policy OP – 08 validation certificate</u>** "The validation certificate is a document intended to ensure accountability and clarify expectations for all parties involved in the provision of an orthotic or prosthetic device." Per current *Prosthetic and Orthotic Device Validation Certificate*: "*Obtain a signed and completed copy of this form for your records.*"
Response	Beyond ensuring accountability and clarifying expectations, the validation certificate is intended to also support: ❖ Transparency ❖ Mutual understanding ❖ Just culture ❖ Client reference ➢ To what was signed and agreed to, in terms of client-specific prosthetic and orthotic, benefit-specific policies and procedures. ❖ Adjudication ❖ Dispute resolution

2. Question/Comment	When are prosthetic and orthotic vendors to use a validation certificate? For example, is it to be used for large items only (new socket) or when other items like liners/sleeves are provided or for everything? Previously it was indicated the validation certificate was not required for billable repairs, modifications, and adjustments.
Current Policy	Scope/requirements remain(s) unchanged per **Policy OP – 08.** **<u>Policy OP – 08 (validation certificate)</u>** "A validation certificate is not required for minor repairs or adjustments or if supplying additional soft supplies after original fitting."

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3. Question/Comment	Previously, it was confirmed the validation certificate and the client declaration forms could not be combined into one form. For clarification, do patients still need to sign the client declaration form or does the new validation certificate also encompass the function of the client declaration?
Response	These two forms remain separate. Both forms are still required. **<u>Client declaration</u>** ❖ Legislation-specific function ❖ Consent to the use of client personal information, and protection of client personal information in accordance with health legislation ➢ *Health Information Act (HIA)* ➢ *Freedom of Information and Protection of Privacy Act (FOIP)* **<u>Validation certificate</u>** ❖ Policy/procedure-specific function ➢ *Policy OP – 08 validation certificate* ❖ *Serves to support:* ➢ **"At time of assessment"** - Acknowledge agreement to the type of device being provided ➢ **"After final provision of the device"** - Acknowledge that fit and trial has been completed

4. Question/Comment	Are prosthetic and orthotic vendors required to use the client declaration form for all repairs or switch to only using the validation certificate?
Current Policy	**<u>Policy GN - 16 (Client Eligibility)</u>** All clients must meet the following criteria to be eligible for AADL benefits [including but not limited to]: Sign the "client declaration." - For any/all new authorizations.
Response	One client declaration is required per authorization.

5. Question/Comment	How are prosthetic and orthotic vendors to handle a situation where a client or their guardian(s) are unable to sign the client declaration or validation certificate?
Current Policy	Scope/requirements remain(s) unchanged per **Policies GN – 07 & OP – 08**, and associated forms.
Response	**<u>Client declaration</u>** ❖ "If the client is <u>unable to sign</u>, provide the **name** and **phone number** of the **individual** who is <u>financially responsible</u> for this <u>client</u> ➢ **"Minor:** Parent/Legal Guardian" ➢ **"Adult:** Informal Trustee/Enduring Power of Attorney/Legal Trustee" **Note:** "This **individual** is also required to <u>sign</u> and <u>print their name</u> on this form on behalf of the client." **<u>Validation certificate</u>**

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	❖ Per Policy OP – 08 (validation certificate) ➢ "Contact the AADL Program Manager if they are unable to sign the validation certificate" ❖ Per the *Prosthetic and Orthotic Device Validation Certificate* ➢ "If [the client is] unable to sign this form, contact the AADL Program Manager to discuss the situation."

6. Question/Comment	What is a suitable "description of prosthetic/orthotic device(s)?" For example, left KAFO vs. left KAFO including tamarack ankle joint, drop lock knee joints, knee cage, and ankle retention strap.
Response	Description/approach is contingent on authorization of benefits: ❖ If a multi-component device is being authorized/issued ➢ Specify by "device," rather than by pertinent itemized component description(s). ❖ If a single component is being issued or a few components are being issued ➢ Specify pertinent itemized component description(s), rather than by device. **Note:** The authorization itself encompasses all benefit items. The description should be understandable to the client. The client should understand what they are receiving and what is actually being funded by AADL.

7. Question/Comment	How should the validation certificate be completed for clubfoot patients with respect to "_____ devices(s) every _____ year(s)"? Clubfoot authorizations include various devices (AFOs & bars) with different frequencies over five years.
Current Policy	**Orthotic Benefits for Clubfoot** [O-APL pp.23 & 24] "These authorizations are exempt from the validation certificate requirements."

8. Question/Comment	The validation certificate can be confusing for bilateral patients as nothing indicates "per side," for example "1 device per 4 years per side" vs "1 device every 4 years."
Response	Currently, if bilateral benefits are authorized under the same authorization, a single validation certificate can be used: ❖ Specify "bilateral" including the specific device types. **Note:** Otherwise, each separate authorization requires a separate validation certificate.

9. Question/Comment	Is AADL now able to accept electronic signatures?
Response	**AADL Bulletin # 97 New AADL Fax Number, Use of Encrypted E-mail and Electronic Signatures** ❖ "AADL will now accept an electronic signature on AADL documents (i.e., client declarations, validation certificates)."

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	❖ "An electronic signature can be created in a number of different ways including electronically drawing the signature on a tablet with a stylus." ❖ "A **signature** of any type indicates **acceptance** and **authentication** of the electronic document." ❖ "The client must electronically sign the document on the day they receive the service." ❖ The AADL vendor, authorizer or specialty supplier must have the capacity to store the electronic document, including the signature, and to provide the document to AADL for audit purposes.

10. Question/Comment	With the acceptance of electronic signatures for the client declaration and validation certificate forms, does AADL also accept a scanned copy of an originally signed form? Will prosthetic and orthotic vendors require special software for these changes and are new regulations being implemented?
Current Policy	***"AADL Bulletin # 97 New AADL Fax Number, Use of Encrypted E-mail and Electronic Signatures"*** ❖ "AADL will now accept an electronic signature on AADL documents (i.e., client declarations, validation certificates)." ❖ "An electronic signature can be created in a number of different ways including electronically drawing the signature on a tablet with a stylus." ❖ "A **signature** of any type indicates **acceptance** and **authentication** of the electronic document." ❖ "The client must electronically sign the document on the day they receive the service." ❖ "The AADL vendor, authorizer or specialty supplier must have the capacity to store the electronic document, including the signature, and to provide the document to AADL for audit purposes."
Response	Clarification provided per reiteration of Bulletin #97. Concerning AADL, no regulations are changing at this time. With respect to the transition to *Alberta Blue Cross,* no new software is required to use the client declaration or validation certificate. , Electronic signatures are not replacing wetsignatures, but are simply another option .

11. Question/Comment	In light of acceptance of electronic signatures, will AADL now provide prosthetic and orthotic vendors with a pdf fillable version of all forms including the client declaration and validation certificate? If so, and in the interest of minimizing the impact of the cost of paper on small business, please engage prosthetic and orthotic vendors in an interactive process of form design, development and testing prior to implementation.
Response	Yes, following transition to *Alberta Blue Cross* later this year, AADL can review prosthetic and orthotic benefit areas.

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12. Question/Comment	Prosthetic and orthotic vendors would like to inquire about electronic p***hysician*** signatures. Are prosthetic and orthotic vendors able to accept electronic p***hysician*** signatures on prescriptions?
Current Policy	***College of Physicians and Surgeons of Alberta*** *- Prescribing: Administration* *A regulated member who uses an online platform (i.e. secure messaging) to transmit prescriptions* ***must****:* ❖ *use only secure system-to-system messaging between an Electronic Medical Record (EMR) system and Pharmacy system or the Alberta Electronic Health Record (Netcare);* ❖ *ensure the EMR has prescription transmission audit capabilities;* ❖ *ensure the information is encrypted; and* ❖ *have a current privacy impact assessment that addresses the use of secure system-to-system messaging.* ***URL:*** *http://www.cpsa.ca/standardspractice/prescribing/.* ***Alberta College of Pharmacy*** *- When is only an electronic signature on a prescription acceptable?* Never, at the moment. *Not acceptable:* ❖ *Prescriptions emailed to you.* ❖ *Prescriptions produced by computer but not signed by the prescriber, or prescriptions with an electronic signature that is not signed or initialed by the prescriber (unless faxed directly from physician's EMR). There are insufficient security measures in place to ensure the validity of prescriptions sent electronically.* **URL:** *https://abpharmacy.ca/faq?shs_term_node_tid_depth=167.*
Response	AADL defers to pertinent externally mandated policies and procedures as required.

13. Question/Comment	Would the prosthetic and orthotic validation certificate also apply to mastectomy prosthesis?
Response	No. The requestor is advised to connect with benefit area manager Lori Harmon for guidance concerning mastectomy prosthetic benefit policy and procedure.

14. Question/Comment	If clients are seen by a prosthetic and orthotic vendor for a liner, do clients have to sign a validation certificate? Can AADL list which prosthetic and orthotic approved product listing codes require a validation certificate [i.e., soft supplies aside]?
Current Policy	**Policy OP – 08 Validation Certificate** A validation certificate is not required for minor repairs or adjustments or if supplying additional soft supplies after original fitting.

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Response	Policy OP – 08 Validation Certificate [re-]emphasized. Beyond policy OP-08, AADL will not be expanding the scope – nor be providing an additional list – of items that do not require the validation certificate. Additional soft supplies are items that are frequently required, as might be minor repairs or adjustments. Given the expected frequency of issuance and the nature of these benefits, a validation certificate is not required for these particular items. For hard supplies or components, it is understood that integration into prosthetic or orthotic device(s) warrants assessment, fitting and trial, thus in conjunction with completion of these performance obligations, a validation certificate is required.

15. Question/Comment	When it is a replacement socket, would you record every _____ blank years?
Current Policy	**<u>Validation Certificate</u>** "I acknowledge that the AADL Program quantity and frequency limits for replacement of my AADL Program funded device(s) is ____ devices(s) every ____ year(s) from the service date and receipt of my AADL Program funded devices"
Response	Quantity and frequency limits may vary across device component specific funding. As such, AADL will consider a different format for ease of use by end-users.

16. Question/Comment	If a patient requires a new shoe elevation, and they are eligible for two pairs a year, is a prescription required with every shoe raise or once a year?
Current Policy	**<u>Policy SE – 01 Program Background</u>** ❖ "A physician who is a member in good standing of the College of Physicians & Surgeons of Alberta must prescribe Shoe Elevation(s)." ❖ "The prescription must be on a generic form and not with any vendor advertising." ❖ "The prescription is valid for three months from the date on the prescription." **<u>Policy SE - 03 Eligibility Criteria for Shoe Elevation Benefits</u>** ❖ A generic prescription from a physician stating: ➢ Diagnosis ➢ Leg length discrepancy measurement ❖ Clients obtain prescription from physician.
Response	Status quo regarding SE-01 and SE-03. Although structural leg length discrepancy may exist, biomechanical changes/implications commensurate with a concomitant functional leg length discrepancy may also co-exist/co-develop; thus reassessment is warranted.

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17.Question/Comment	The transfer of care (TOC) policy is referenced within the validation certificate. How is a transfer of care approved by the AADL Program? Are transfer of care procedures required when a client is fully eligible for new treatment and simply desires a "change of scenery?" Who is protected by a transfer of care?
Current Policy	**Policy OP – 06 Orthotic and Prosthetic Specialty Suppliers** P&O vendors: ❖ Check E-Business to verify if client has been provided prosthetic and orthotic benefits by AADL. ➢ If yes, contact AADL benefit clerk to find out who was the previous specialty supplier. Refer client back to original specialty supplier for ongoing service and follow-up with the device. ❖ If client refuses to return to previous provider, the specialty supplier must not provide service to the client unless the client is willing to fund the services privately. ➢ Contact previous specialty supplier to discuss transferring care to the new specialty supplier if client wishes to switch suppliers. ❖ Advise AADL Program Manager if agreement of a transfer of care is reached. ***Prosthetic and Orthotic Device Validation Certificate*** "[Client] acknowledge[s] that in order to change [their] Prosthetist/Orthotist for AADL Program funded prosthetic/orthotic device(s), a transfer of care be established and approved by the AADL Program."
Response	Pragmatism is required. ❖ In many circumstances, a transfer of care should be "approved," supplier-to-supplier. ❖ However, duplicate benefit funding circumstances may arise due to a transfer of care. If this scenario arises, the AADL Program Manager should be contacted directly. In many circumstances, a transfer of care should be approved supplier to supplier. The validation certificate protects clients, prosthetic and orthotic vendors, and AADL.

18. Question/Comment	Where a transfer of care is concerned, there is rarely ever a phone conversation between prosthetic and orthotic vendors. Usually, only a fax is provided with a client's name and no accompanying reason/rationale. Prosthetic and orthotic vendors believe that once a client is beyond that quantity and frequency period [i.e., typically 2 years] for a device(s), clients should be able change their vendor.
Current Policy	**Policy GN – 08 Explaining Policies and Procedures to Clients** ❖ "Client choice of vendor" ➢ "Ensure clients are aware that they have a choice of a minimum of three (3) vendors (where available), and that a list of all AADL approved vendors for the assessed benefit is available." **Policy OP – 06 Orthotic and Prosthetic Specialty Suppliers**

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	❖ "Clients Choice of Specialty Supplier" ➢ "Clients have a choice of specialty supplier, unless they are inpatients at a health care facility that employs a publicly funded specialty assessor." ➢ "Specialty suppliers are responsible to confirm the client is not being provided benefits by different specialty suppliers before submitting authorizations to AADL." P&O Vendors: ❖ Check E-Business to verify if client has been provided prosthetic and orthotic benefits by AADL. ➢ If yes, contact AADL benefit clerk to find out who was the previous specialty supplier. Refer client back to original specialty supplier for ongoing service and follow-up with the device. ❖ If client refuses to return to previous provider, the specialty supplier must not provide service to the client unless the client is willing to fund the services privately. ➢ Contact previous specialty supplier to discuss transferring care to the new specialty supplier if client wishes to switch suppliers. ❖ Advise AADL Program Manager if agreement of a transfer of care is reached. ***Prosthetic and Orthotic Device Validation Certificate*** "[Client] acknowledge[s] that in order to change [their] prosthetist/orthotist for AADL Program funded prosthetic/orthotic device(s), a transfer of care be established and approved by the AADL Program."
Response	Pragmatism is required. ❖ In many circumstances, a transfer of care should be "approved" supplier-to-supplier. ❖ However, duplicate benefit funding circumstances may arise due to a transfer of care. If this scenario arises, the AADL Program Manager should be contacted directly. In many circumstances, a transfer of care should be approved supplier to supplier. Overall, "Client choice of vendor" and "Clients Choice of Specialty Supplier" should be upheld per **Policies GN – 08 & OP – 06.**

19. Question/Comment	Prosthetic and orthotic vendors acknowledge that there are also issues of patient privacy to consider when a transfer of care is initiated for a prosthetic and orthotic device(s).
Current Policy	AADL agreement(s), and pertinent policies/regulations – HIA and FOIP. ***Documentation:*** *The Specialty Supplier will: maintain all documentation in accordance with all applicable laws, including but not limited to laws that are intended to protect Clients' information and privacy.*

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	16. ***INFORMATION AND PROTECTION OF PRIVACY:*** (a) *The Specialty Supplier acknowledges that this Agreement and all reports and other records submitted to the Minister will be subject to the access and disclosure provisions of the Freedom of Information and Protection of Privacy Act or the HIA, as applicable.* (b) *The Specialty Supplier is an "Affiliate", as that term is defined in the HIA, of the Minister and Alberta Health for the purposes of this Agreement and agrees that:* i. *the Specialty Supplier shall not collect Health Information unless such collection is necessary to carry out the obligations of the Specialty Supplier under this Agreement or the collection is expressly authorized by the Province in writing in advance of any collection taking place;* ii. *the Specialty Supplier shall cause its employees, agents or subcontractors to use the Health Information solely for the purposes of this Agreement and shall limit access to the Health Information to only those employees, agents and subcontractors who have a need to know;* iii. *the Specialty Supplier shall cause its employees, agents or subcontractors to undergo HIA training and to adopt the Health Information Act Guidelines and Practices Manual found at http://www.health.alberta.ca/about/Health-Information-Act.html*; iv. *the Specialty Supplier agrees to be fully and solely responsible for the actions of its directors, officers, employees, agents and subcontractors with respect to the collection, storage, use or disclosure of the Health Information;* v. *the Specialty Supplier shall protect the Health Information against such risks as unauthorized access, use, disclosure, destruction or alteration and return to the Minister or destroy, in accordance with instructions provided by the Minister, any Health Information upon expiry or termination of this Agreement;* vi. *the Specialty Supplier shall not store, use or disclose the Health Information in the United States.* vii. *the Specialty Supplier shall not store, use or disclose the Health Information outside Alberta, but within Canada, unless expressly authorized in writing by way of an executed Section 8 Agreement attached at Schedule "A".* viii. *the Specialty Supplier shall immediately advise the Minister of any actual or potential breach of the HIA by the Specialty Supplier, its directors, officers, employees, agents or any subcontractors upon the Specialty Supplier becoming aware of such actual or potential breach;*
Response	AADL re-iterated pertinent policies/regulations – *Health Information Act* (HIA) and *Freedom of Information and Protection of Privacy Act* (FOIP).

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20. Question/Comment	Does a transfer of care have to be recorded on the AADL e-business authorization? If so, how much detail is required?
Current Policy	**Policy OP – 06 Orthotic and Prosthetic Specialty Suppliers** • Contact the AADL Program Manager for advice as required. • Advise AADL Program Manager if agreement of a transfer of care is reached.
Response	Clinicians/businesses are responsible for documenting pertinent information. Should such information interface with AADL funding – in particular, matters concerning circumstances of TOC – it would be prudent to document information accordingly. Contact the AADL benefit area manager to advise of the transfer.

21.Question/Comment	For prosthetics, specialty suppliers/assessors may be dispensing items in stages. Clients sign the validation certificate at the time of initial assessment for all of the components that a prosthetist thinks that clients will require, thus all items are listed under one authorization and require one validation certificate. What form(s) do clients need to sign as they receive the components?
Current Policy	**Policy OP - 02 Client Eligibility and Authorization Process** "Fit the client with the device and permit an opportunity for a trial to occur. Once completed, have the client sign the final section of the validation certificate." **Policy OP – 05 Specialty Assessors for Orthotic and Prosthetic Benefits** "Once fitting and trial are completed, have client sign the final section of the validation certificate for receipt of **all** components/devices." **Policy OP – 08 Validation Certificate** The validation certificate is a two-part form. The client will sign this form on two separate occasions: 1. At time of assessment: acknowledging agreement to the type of device being provided. 2. After final provision of the device: acknowledging that fit and trial has been completed. The specialty supplier must not submit a claim for the **final** components or procedures until **all** sections of the validation certificate are signed by the client, which is considered the service date for these components and/or procedures.

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