PAAB Tags 2021

QUARTERLY REVIEW

A quarterly review of the eFiles tag report

Total number of submissions

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2666	2814	2462	2570

Total number of client tags (prior to validation)

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
28	8	4	8

Therapeutic area distribution

QUARTER 1		QUARTER 2		QUARTER 3		QUARTER 4	
9	*Oncology*	2	*Dermatology/ Immunology*	2	*Respiratory*	4	*Cardiovascular*
7	*Diabetes*	2	*COPD/Asthma*	1	*Cardiovascular*	2	*Women's Health*
4	*Dermatology/ Immunology*	1	*Hospital Injectables*	1	*Biologics/Immuno modulators*	1	*Oncology*
1	*Neurological (ADHD)*	1	*Neurological (ADHD)*			1	*Other*
1	*Endocrine & Metabolic*	1	*Oncology*				
1	*Osteoporosis*						

Total number of tags deemed valid following internal review

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
8	2	1	6

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Validated tag breakdown

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4 *New issues were raised late in the review process*	2 *Inconsistencies with historic approvals for the same brand or a different brand were noted*	1 *Particularly helpful discussion or action*	3 *Particularly helpful discussion or action*
1 *Inconsistencies with historic approvals for the same brand*			1 *New issues were raised late in the review process*
1 *Late correspondence impacted the client*			1 *Consider changing the code guidance*
1 *Particularly helpful discussion or action*			1 *Issue with level of expertise*
1 *Issue with level of expertise*			

NEW: Q4 PAAB action taken:

The issue identified as requiring code/guidance change was reviewed and assessed. While the formulary guidance document, Provincial Formulary Coverage Statements, was deemed to be accurate, a hyperlink was added to facilitate access to related documents (i.e. "*Please also refer to the Advisory regarding use of RAMQ in APS for additional guidance on Quebec provincial formulary claims.*")

Other areas identified were the communication of the differences between past files and current files, and the requirements for case studies. The former was addressed by further coaching the Reviewer in communicating these differences, and the latter led to reminder discussion on the PAAB process for reviewing case studies (with the Reviewer and a member of the Senior Reviewer team).

It is encouraging to see so many positive tags. The positive feedback was shared with the Reviewers and acknowledged to the team to help encourage our continued commitment to customer service.

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Q3 PAAB action taken:

With only one valid tag this quarter, no additional action was taken.

A reminder that the tagging system is the most effective way to help identify inconsistencies, training opportunities, and areas of the Code where changes could be considered.*

Q1-Q2 PAAB action taken:

A trend across all tags, demonstrated that clarity around when review practices have changed, may have provided a smoother route to acceptance. In the last year, there have been a number of new guiding documents posted to the PAAB website, to provide clarification on review practices or advise of changing practices such as the review of Kaplan Meier analyses. As a result of both valid and unvalidated tags, we've taken the time to remind reviewers to pre-emptively convey these changes or direct clients to new documents early on in the review process so as to reduce the perception of inconsistencies.

We've also increased our frequencies and channels of external communications. You can find PAAB on LinkedIn, Twitter (ThePAAB), subscribe to the Forum to be notified any time a new document is posted, and subscribe to email communications.

Technical functions of the eFiles and PDF editor program were covered with the team to ensure a high level of expertise and proficiency.

Most common reasons tags could not be validated

Submission errors – It's important to ensure that backfiles are quoted for all previously approved content on the initial submission. This helps to maintain consistency and allows the reviewer a chance to pre-emptively explain why content perceived to be previously approved, may not be acceptable in a new or revised context.

Incomplete Tags – When not enough information is provided, it can be difficult to validate the tag. Please take a few moments to ensure that all the relevant information is presented so that the tag can be validated.

Confidence in confidentiality

As a reminder, client tags trigger internal audits for validation by PAAB's Senior Reviewer of Pre-clearance Services, Yin Man. Any tags pertaining to Yin are validated by the Commissioner and removed from the report provided to Yin. No Reviewer or Senior Reviewer is EVER aware of tags generated by clients. You can be confident in the confidentiality of the tagging system. For additional reassurance, the tagging system, tag assessments, and documented actions taken will periodically be reviewed by an external auditor.

If you'd like to learn more about the client tagging system, check out the Client Tagging System Advisory. You'll also find links to useful videos on tagging a review and tagging phone calls.

Is there more information you would like to know and see in the next quarterly update? Let us know on the Forum.