

## **Impact of the Avastin Patient Access Scheme (APAS)**

Following feedback from the committee considering some uncertainty around the administrative costs of the scheme, Roche has carried out interviews with experts in the field of Pharmacy and Finance to understand the administrative burden of APAS and held an Advisory Board meeting in London to validate the findings and to confirm the time estimates for the administrative tasks (Appendix 1).

To minimise these costs, Roche are working with a third party agency to develop a web-based data-entry tool, which will have reporting functions to ease and reduce the administrative burden for each department. Unlike currently used web-based systems, which are simple data-entry tools to ensure receipt of the appropriate rebate, the APAS web-based system will be a fully functional real time reporting tool that will provide a number of user defined time-saving reports required for the administration of APAS (Appendix 2).

Currently, there is some variation in the effectiveness of the systems and processes adopted by Trusts and PCTs to manage PAS. The figures outlined in this document represent what Roche believe, following consultation with stakeholders and the Advisory Board, to be a comprehensive overview of the likely administrative burden of effectively managing the APAS.

The assumptions in this document regarding the time required to perform the APAS administrative functions are based on Roche:

1. Providing a web-based administration tool with the specification listed in Appendix 2.
2. Providing reports, listed in Appendix 2, which reduce the administrative burden for key departments.
3. Paying rebates, usually within 14 days but always within 30 days of data receipt.

Following advice from NHS stakeholders, Roche have divided the APAS costs into one off set-up and ongoing costs.

### **A. APAS Set-up Costs ( One Off )**

1. Initial implementation meetings
2. Initial system set-up

### **B. APAS Ongoing Costs**

1. Pharmacy Administration
2. Trust finance management
3. PCT finance management
4. Query management

## A APAS Set-up Costs (one off costs)

### A1. Initial Implementation Meetings

Initial Set up Meetings (one per trust) between key stakeholders within the Trust and PCT, including clinicians, pharmacists, finance and PCT finance, The objective of these meetings would be to investigate the implications of APAS, decide on the most appropriate way of administering the scheme, assign roles and responsibilities and agree the 'rules' of how APAS should be implemented and queries resolved. The Advisory Board suggested that two hours of meetings and one hour of pre meeting preparation would be required to meet these goals .

**Table A1. Initial Implementation Meetings**

Role	Grade	Pre-meeting preparation time (hours)	Meeting time (hours)	Total time (hours)
Clinician	8	1	2	3
Procurement Pharmacist	8	1	2	3
Chief Pharmacist	8	1	2	3
Oncology Pharmacist	8	1	2	3
Trust Finance	6	1	2	3
PCT Finance	6	1	2	3
Operations Manager	6	1	2	3

### A2. System Set-up Costs

1. Sign the contractual agreement between Roche and the Trust.
2. Configure the oncology electronic prescribing system (e.g. EPS, ChemoCare) and create a report definition to capture scheme activity.

**Table A2. System Set-up Costs**

Activity	Role	Grade	Time (hours)
Agree and sign contract	Chief Pharmacist	8a	2
Configure oncology EPS/ChemoCare system	Chief Pharmacist	8a	1-2

## B APAS Ongoing Costs

### B1. Ongoing Pharmacy Costs include :-

1. Enrolment of patients in APAS web-based reporting tool.
2. Updating patient-level data – this can be entered by the pharmacist with each cycle of treatment or batched and entered directly from the oncology EPS either monthly or quarterly. Roche has introduced this flexibility in response to feedback from stakeholders.
3. Reconciliation – pharmacy to reconcile discrepancies between oncology and patient-level data in the web-based scheme to ensure that all eligible patients and treatment cycles have been entered into the scheme.
4. Ensure that the “rules” of the scheme governing the fixed price, free of charge oxaliplatin and the 12 month treatment cap are applied . This involves implementing the process which tracks the rebate, and free of charge stock from pharmacy to the PCT. These rules may be automated or involve manual overrides of the pharmacy systems ( eg. JAC / Ascribe ) . This process will have been agreed at the initial implementation meetings . Roche will provide a detailed report detailing the rebate owed to each patient to facilitate this process.
5. Ensure that the credit note is coded to the oncology department and a breakdown of the credit to patient level is sent to the finance department to pass on the credit to PCTs (this can be assisted by accessing the web-based reporting tool).

**Table B1. Ongoing Pharmacy Costs**

Activity	Role	Grade	Time (minutes)	Frequency
Enrol patients	Oncology Pharmacist	6	10	Per patient
Update patient-level data per treatment cycle	Oncology Pharmacist or Pharmacy Technician	6	5	Per cycle (or batched)
Reconciliation Scheme Rules are applied	Pharmacy Operations Manager	6	25	Monthly (batched)
Code credit note and send to finance				

### B2. Ongoing Trust Finance Costs

Hospital Trusts Accounts-Payable team to manage the credit note against the invoice. Roche will commit to processing the credit note usually within 14 days but always within 30 days of data receipt. This follows feedback from Trusts on the requirement for prompt payment of rebates.

Hospital Trusts Management accountants to ensure that the credit note total is equivalent to the individual patient rebate.

Hospital Trust Finance accounts-receivable team to ensure that the credit is coded against the correct PCT or ensure that the PCT is charged the correct:

- Net price
- Gross price followed by credit note
- Offset cost of future invoice.

Typically, these activities would be carried out as a batch on a monthly basis using current systems and processes for the management of PCT-level rebates with other financially based PAS.

**Table B2. Ongoing Trust Finance Costs**

Activity	Role	Grade	Time (minutes)	Frequency
Manage credit notes against invoices	Management Accountant	6	5	Monthly
Credit note coded against correct PCT	Financial Accounts	6	30	Monthly

### **B3. Ongoing PCT Finance Costs**

Ensure that the flow of credit from the Trust to the PCT is accounted for appropriately. Typically, these activities would be carried out as a batch on a monthly basis using current systems and processes for the management of rebates with other financially based PAS.

**Table B3. Ongoing PCT finance costs**

Activity	Role	Grade	Time (minutes)	Frequency
Manage credits from trust as appropriate	Financial Accounts	6	30	Monthly

### **B4. Query Management**

In addition to the costs detailed above, which have been informed by the Advisory Board, Roche has also included time for the management of potential queries. Feedback from stakeholders suggests that these queries are likely to manifest themselves as phone calls or e-mails between finance, the Oncology Pharmacist or Purchasing and Roche. Roche has therefore included a per-patient time allowance for resolution of these queries. Roche would expect that the number of queries would decrease over time as Trusts become used to managing the scheme. However, Roche has included this 'cost' for every patient treated.

**Table B4. Query Management**

Activity	Role	Grade	Time per patient for duration of scheme (minutes)
APAS query management	Various	6	15

## Appendix 1

### Roche NHS Advisory Board: Implementing Patient Access Schemes

***Please note that the following information is privileged and confidential. It is provided on the understanding that it will be treated in confidence and will not be divulged to any third parties.***

Roche held an NHS Advisory Board on Implementing Patient Access Schemes in London on Wednesday 25 November.

The Advisory Board comprised the following advisors:

*Chair*

[REDACTED], Pharmacy Business Services Manager, [REDACTED]

*Advisors*

[REDACTED], Procurement Pharmacist, [REDACTED]  
[REDACTED], Pharmacy Procurement Services Manager, [REDACTED]  
[REDACTED], Oncology Pharmacist, [REDACTED]  
[REDACTED], Pharmacy Operations Manager, UCLH  
[REDACTED], Specialist Pharmacist, [REDACTED]  
and  
[REDACTED], Network Pharmacist, [REDACTED]

The objectives of the meeting were to provide insight into the administrative issues surrounding PAS, to review the administrative requirements of APAS and to confirm that the time estimates proposed by Roche for the APAS administrative requirements were reasonable.

## Appendix 2

### APAS Web-based Administration and Reporting Tool

Roche are currently developing an APAS web-based reporting tool that will use an encrypted NHS or hospital number (depending on Trust requirements) to reduce the administrative burden associated with APAS implementation. Roche are working in conjunction with an agency that has worked on web based schemes for PAS within the NHS previously

While the paper-based option will be retained, Roche envisage that the majority of Trusts will prefer the simplicity and functionality of the web-based administration and reporting tool.

Roche will grant administration and viewing rights to appropriate staff members. Administration rights would typically be granted to Pharmacy with viewing rights to Trust/PCT finance staff.

#### Data input required to enrol a new patient into the scheme

1. NHS or hospital number (encrypted: see details below)
2. PCT (if this is required by a Trust for tracking the rebate)
3. Date
4. Patient weight
5. Dose of Avastin
6. Dose of oxaliplatin

The following confirmations will involve a simple 'tick box':

1. Confirmation that the patient is not taking part in a clinical trial.
2. Confirmation that the patient is being treated for first-line metastatic colorectal cancer and that the disease has not progressed.
3. Confirmation that the Avastin is being purchased from Roche or a compounding company.

#### Data input required to facilitate rebate claim:

1. Vials of Avastin used in the treatment cycle.
2. Vials of oxaliplatin used in the treatment cycle.
3. Number of treatment cycles claimed.
4. Date of claim period.

The following confirmations will involve a simple 'tick box':

1. Confirmation that Avastin has been administered for all cycles in the treatment claim period.
2. Confirmation that oxaliplatin is being used in conjunction with Avastin.
3. Confirmation that the registration details have not changed.

## **Reports function by NHS/hospital number to facilitate administration of scheme**

These reports are designed to ensure that there is a simple audit trail so that rebates can be tracked between pharmacy, oncology, finance and the PCT (Roche will consult with individual Trusts on data requirements for successful implementation of the scheme).

The report fields are:

1. NHS or hospital number (encrypted)
2. PCT
3. Vials of Avastin and oxaliplatin administered
4. Rebates claimed/pending/paid by NHS/hospital number
5. Cycles claimed to date
6. Invoice numbers of Avastin ordered (if purchased direct from Roche)
7. Total rebate by PCT (if required)
8. Outstanding data (e.g. unclaimed cycles/missing data etc).

## **Encryption of the patient NHS/hospital number**

1. As a hospital administrator enters a patient's data onto the system, a unique encryption code will be automatically assigned to the data by the system.
2. The system has its own secondary application-wide encryption code.
3. The patient NHS/hospital number will then be then automatically converted by the system using a combination of the two codes (the unique patient code and the system application code) into encrypted data.
4. The encrypted data will then be stored in the database.

This encryption process means that if the database is accessed directly, the fields containing the patient NHS details appear as a random series of numbers and letters.

Without possessing both the application-wide encryption code and the individual patient encryption code, the data is almost impossible to de-encrypt, thus safeguarding the patient NHS number from external viewing.

This method of encryption is already in use within the NHS for another web-based PAS data-entry system to ensure patient confidentiality.