Croydon Health Services NHS
NHS Trust

GUIDANCE ON VACCINATION REQUIREMENTS IN ADULT PATIENTS STARTING BIOLOGIC AGENTS

Version:	1.0
Ratified by: ***(NB: All Procedural Documents which include details of drugs or their management must be approved by the Medicines Management Committee)***	Medicines Management Committee Croydon Prescribing Committee
Date ratified:	03/12/2020
Approving Committee/Group (Date)	MMC
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Lead Director:	Stella Vig, Clinical Director, Integrated Surgery, Cancer and Clinical Support
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Related CQC Domain ***(Please tick)***	■ Safe ■ Effective ■ Caring ■ Responsive ■ Well-Led
Relevant Standards(e.g. HSE, Health and Social Care Act)	N/A

Acknowledgements	
Key Words	Vaccines, immunisation, biologics,

EXECUTIVE SUMMARY

This guideline is intended to provide guidance to Croydon Health Service's staff on the vaccination requirements before starting biological therapy.

The document contains information on the current immunisation schedule and information on vaccines that are contraindicated in patient's taking biological agents.

CONTENTS

1 INTRODUCTION

Public Health England recommends eligible individuals anticipating immunosuppressive therapy including biologic agents, should ideally be assessed for vaccine eligibility before starting treatment that may contra-indicate future vaccination. Biologic agents can be started by various clinical specialities including rheumatology, gastroenterology and dermatology.

Biologic agents used at Croydon Health Services include:

- TNF-α inhibitors (Adalimumab, Etanercept, Infliximab, Certolizumab and Golimumab)
- JAK inhibitors (Baricitinib and Tofacitinib)
- Rituximab
- Interluekin-6 inhibitors (Tocilizumab and Sarilumab)
- Interluekin-7 inhibitors (Brodalumab, Ixekizumab and Secukinumab)
- Interluekin-23 inhibitors (Tildrakizumab and Guselkumab)
- Abatacept
- Vedolizumab
- Ustekinumab

2 PURPOSE

The aim of this guideline is to support clinicans at CHS to ensure vaccination status is reviewed in a standardised format prior to initiating a biological agent. This guideline will also highlight vaccines that are contraindicated in these patients in line with The Immunisation against infective disease (Green Book) and British Society of Rheumatology.

This guideline does not cover paediatric or maternity patients.

It should also not be used as a substitute for individual biologic medicine SPC, nor the national guideline on vaccinations. Clinicians are encouraged to check SPC of medicines and be up to date with the relevant national guidance on vaccinations.

3 DEFINITIONS

British Association of Dermatologists (BAD) – specialist medical society for dermatology

British Society of Rheumatology (BSR) – specialist medical society for rheumatology and musculoskeletal professionals

British Society of Gastroenterology (BSG) - specialist medical society for gastronenterology

Croydon Prescribing Committee (CPC) – Joint prescribing committee for Croydon Health Services

Disease-Modifting Anti-Rheumatic Drugs (DMARDs) – drugs act by altering the underlying disease to slow down disease progression

European Crohn's and Colitis Organisation (ECCO) – a European association focusing on inflammatory bowel disease

General Practitioner (GP)- a doctor based in the community who treats patients

Hepatitis B Virus (HBV) – a virus that causes life threatening liver infection both acute and chronic.

Hepatitis C Virus (HCV)- a virus that causes life threatening liver infection both acute and chronic.

Immunoglobulin G (IgG) – the most common antibody found in humans to help protect against infection

Summary Product Charateristics (SPC) – a legal document release by the manufacturer containing factual information about a medicinal product

Varicella Zoster Virus (VZV) – a virus known to cause chickenpox and shingles

World Health Organisation (WHO) – a specialised agency of the United Nations responsible for international public health

4 ACCOUNTABILITIES AND RESPONSIBILITIES

Prescribers are responsible for adhering to the guidelines when caring for patients

Nursing staff are responsible for adhering to the guidelines and alerting prescribers of the guidelines

Trust pharmacists are responsible for alerting prescribers of the guidelines, encouraging adherence and reporting non-adherence to the directorate pharmacist**.**

5 PROCEDURE/COURSE OF ACTION REQUIRED

5.1 Seasonal influenza

Those eligible for influenza vaccine (on the basis of age or clinical risk) should be vaccinated each winter, usually between September and March, although vaccination may still be of some benefit if given later. The annual letters on the influenza programme should be consulted for eligibility criteria.

The injected influenza vaccine given to adults contains inactivated influenza viruses.

5.2 Vaccinations required prior to initiating biological agent

Individuals anticipating immunosuppressive therapy should ideally be assessed for vaccine eligibility before starting treatment that may contra-indicate future vaccination.

Patients' receving biological therapies or high doses of immunosuppressive therapies should not be given live vaccines because of the risk of severe or fatal infections *(table 1).* It is recommended these patients, if possible, be brought up to date with all vaccinations in agreement with current vaccination guidelines prior to initiating biological therapy. See *appendix B* for the full immunisation regime.

Table 1: List of live vaccines used in adults that are available in the UK[(1)]

Vaccine	Brand name
Measles, Mumps and Rubella vaccine	Priorix or MMRVaxPro
Shingles (Zoster) vaccine	Zostavax
BCG vaccine	
Oral typhoid vaccine	Ty21a
Varicella vaccine	Varilrix or Varilvax
Yellow Fever vaccine	

The Immunisation against infectious disease (Green Book)[(1)] clearly lists the schedule for the UK's routine immunisation programme in adults (excluding catchup campaigns) including the following:

• 65 years old Pneumococcal polysaccharide vaccine (PPV) – Single dose injection
• 65 years of age and older- Inactivated influenza vaccine - One injection annually
• 70 - 79 years old Shingles vaccine – Single dose injection

Vaccination of individuals with unknown or incomplete immunisation status

For a variety of reasons, some individuals may present not having received some or all their immunisations or may have an unknown immunisation history. In these circumstances, the following should be considered:

- Where an individual born in the UK presents with an inadequate immunisation history, every effort should be made to clarify what immunisations they may have had.

  Anyone who has not completed the routine immunisation programme as appropriate for their age should have the outstanding doses as per the Immunisation against infectious disease (Green Book).

- If an individual coming to the UK does not have a documented or reliable verbal history of immunisation, they should be assumed to be unimmunised and a full course of required immunisations should be planned.

- Individuals coming from areas of conflict or from population groups who may have been marginalised in their country of origin (such as refugees, gypsy or other nomadic travellers) may not have had good access to immunisation services. Check with the Croydon Rainbow Health Centre if the patient is known to their services and whether the centre have already vaccinated the individual. Where there is no reliable history of previous immunisation, it should be assumed that any undocumented doses are missing and the UK catch-up recommendations for that age should be followed.

- Individuals coming to the UK who have a history of completing immunisation in their country of origin may not have been offered protection against all the antigens currently offered in the UK.

  Current country-specific schedules are available on the WHO website under immunisation monitoring.

  Refer to Appendix C for further details

5.3 Timing of vaccinations prior to commencing biologic therapy

As live vaccines replicate after administration, ideally individuals who have received a live vaccine should wait until their immune response has been established to receive immunosuppressive therapy. For most viral live vaccines a period of up to four weeks should be sufficient. However, as the vaccine viruses are generally attenuated, immunosuppressive treatment should not be delayed if this could result in worsening of the underlying condition. In such situations, additional measures such as antibody-testing, monitoring for evidence of infection, the administration of antivirals or immunoglobulin may be considered. Specialist advice should be sought on a case-per-case basis.

Vaccination of immunosuppressed individuals should only be conducted in consultation with an appropriate specialist. Inactivated vaccines cannot replicate and so may be administered to immunosuppressed individuals, although they may elicit a lower response than in immunocompetent individuals.

<u>Varicella Zoster Virus</u>

- The BSR, BSG and BAD recommend patients without a clear history of chickenpox, shingles or receipt of two doses of varicella vaccine should be tested for VZV IgG.

- Prior to commencing biologic therapy and provided that there are no contraindications:

    - In seronegative patients consider recommending administration of two doses of varicella vaccines to prevent chickenpox infection[(2)]
    - In seropositive individuals consider recommending administration of single dose herpes zoster vaccine to prevent shingles infection

- The BSR recommends patients >50 years should undergo vaccination against herpes zoster (HZ) at > 14 days before starting biologic therapy. This is assuming there are no contraindications (e.g. treatment within the past 3 months with >40 mg prednisolone per day for >1 week, >20 mg prednisolone per day for >14 days, methotrexate >25 mg/week, azathioprine >3.0 mg/kg/day)

- JAK inhibitors (Baricitinib and Tofacitinib)
    - prophylactic zoster vaccination (shingles vaccine) should be considered in accordance with vaccination guidelines.
    - Particular consideration should be given to patients with longstanding rheumatoid arthritis who have previously received two or more biological DMARDs. If a live zoster vaccine is administered; it should only be administered to patients with a known history of chickenpox or those that are seropositive for varicella zoster virus (VZV). If the history of chickenpox is considered doubtful or unreliable it is recommended to test for antibodies against VZV.

5.4 Additional testing required prior to initiating biologic therapy

Tuberculosis

Tuberculosis, including reactivation and new onset of tuberculosis, has been reported in patients receiving biologic therapy. Patients must be referred to the respiratory team for latent TB screening before initiation of a new biologic agent. Upon referral, the patient will have the chest X ray, the mantoux test, the quantiferon test, the clinical assessment and decision made for treatment with antibiotics.

Before initiation of **any** biologic therapy, all patients must be evaluated for both active or inactive ("latent") tuberculosis infection.

This evaluation should include:

- a detailed medical assessment of patient history of tuberculosis or possible previous exposure to people with active tuberculosis and previous and/or current immunosuppressive therapy
- Appropriate screening tests i.e. tuberculin skin test (Mantoux test), chest X-ray and quantiferon test should be performed in all patients

If active tuberculosis is diagnosed, biologic therapy **must not be initiated**

The benefit/risk balance of therapy should be very carefully considered for the following:

- If latent tuberculosis is suspected, a physician with expertise in the treatment of tuberculosis should be consulted.

- If latent tuberculosis is diagnosed, appropriate treatment must be started with anti-tuberculosis prophylaxis treatment before the initiation of biologic therapy, and in accordance with local recommendations.

- Use of anti-tuberculosis prophylaxis treatment should also be considered before the initiation of biologic therapy in patients with several or significant risk factors for tuberculosis despite a negative test for tuberculosis and in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed.

Patients should be instructed to seek medical advice if signs/symptoms suggestive of a tuberculosis infection (e.g., persistent cough, wasting/weight loss, low grade fever, restlessness) occur during or after therapy with biologic therapy.

Hepatitis B and C Infection (HBV and HCV)

Prior to starting Biologics, patients should be screened for HBV and HCV infection. For patients who test positive for HBV or HCV infection, consultation with a physician with expertise in the treatment of hepatitis is recommended.

In addition, BSR, BSG and BAD all recommend individuals with ongoing risk factors for hepatitis B infection (see table 2) should undergo immunization prior to starting anti-TNF treatment. Hepatitis B vaccines are inactivated vaccines and therefore do not contain live organisms and cannot cause hepatitis B in an immunosuppressed individual. However, there is circumstantial evidence indicating that TNF blockade may decrease responses to the hepatitis B vaccine.

Therefore, though it is safe to give hepatitis B vaccine to a patient on anti-TNF treatment, if possible, the first hepatitis B vaccine should be given prior to commencing anti-TNF therapy.

Studies to date continue to show that biologic (especially anti-TNF) therapies do not have a detrimental effect on HCV infection, but it would be prudent to work closely with a hepatologist and arrange monitoring.

Table 2: Risk factors for hepatitis B and C infection(2)

People at higher risk of hepatitis B and C infection
People born or brought up in a country with an intermediate or high prevalence of chronic hepatitis B or C. This includes all countries in Africa, Asia, the Caribbean, Central and South America, eastern and southern Europe, the Middle East and the Pacific islands
People who have ever injected drugs
Men who have sex with men (particularly, HIV-positive men who have sex with men are at a greater risk of hepatitis C)
People in close contact with someone known to be chronically infected with hepatitis B or C
Prisoners, including young offenders

Human Immunodeficiency Virus (HIV)

There is no evidence base to support the testing of all patients before commencing biologic therapy. The prevalence of HIV in most parts of the UK is low and the likelihood of a positive result in an individual without risk factors is very low. The recent NICE guideline NG60 summarizes the groups in which an HIV test should be offered; it does not advise routine testing in all individuals prior to immunosuppressive agents, unless risk factors are present.

If considering the use of biologic therapy in HIV positive patients, this should be discussed with an HIV specialist. It should be borne in mind that a reasonable benefit to risk ratio for HIV patients exists with anti-TNF therapy if HIV infection is controlled (CD4+ count >200 cells/mm3 and viral load undetectable) and anti-TNF is given in combination with highly active anti-retroviral therapy. Nevertheless, patients with HIV receiving Biologic therapy require close monitoring of viral load and CD4 count. Treatment changes should be made in light of results, with guidance from an HIV specialist[(2)].

5.5 Summary of processes for initiating a biologic therapy

Prior to starting a biologic agent, clinicians to ensure the following is carried out (also see appendix D):

- Patient is screened for TB (referral to Respiratory team), HBV or HCV HCV (if positive refer to Gastroenterology), and cleared to be started on Biologics
- Patient's requirement for vaccines is assessed
- If any vaccines are required, the patient is informed and it is communicated to the patient's GP through notification letter (see appendix E).
- Confirmation that the patient has had the required vaccines is documented
- Biologics Investigations and Vaccination Checklist form (see appendix C) is completed and uploaded onto the patient's notes on CRS Millennium

6 MONITORING COMPLIANCE

The following table may be useful for ensuring key requirements are monitored.

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Acting on recommendations and Lead(s)	Change in practice and lessons to be shared
Changes/ Updates to guidelines	Lead Pharmacist – Medicines Management	Updates from the Green Book, specialist groups and SPC of individual Biologics	Every 3 years	Report to MMC	Lead Pharmacist – Medicines Management	Discussed at MMC and communicated to the relevant groups
Compliance to checklist	Lead Pharmacist – Medicines management	Audit the appendix checklist compliance	Every 2 years	Report results to relevant specialist teams	Lead Pharmacist – Medicines management	Discussed at relevant committees

7 REFERENCES

1) Immunisation against infectious disease: The Green book (2013). Last accessed [10th July 2020]

2) The British Society for Rheumatology biologic DMARD safety guidelines in inflammatory arthritis. Christopher R Holroyd, Rakhi Seth, Marwan Bukhari, et al. Rheumatology, Volume 58, Issue 2, February 2019, Pages e3–e42. Last accessed [10th July 2020]

3) National Rheumatoid Arthritis Society: Immunisation for people with rheumatoid arthritis (2015). Last accessed [10th July 2020]

4) NICE guideline [NG60] HIV testing: increasing uptake among people who may have undiagnosed HIV (2016).

5) British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. Lamb CA, KennedyNA, Raine T, et al. Gut Epub. doi:10.1136/gutjnl-2019-318484. Last accessed [14th August 2020].

6) British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. C.H. Smith, Z.K. Jabbar-Lopez, Z.Z. Yiu, T. Bale et al. Dermatol 2017; 177: pages 628-636. Last accessed [14th August 2020]

8 ASSOCIATED DOCUMENTATION

- Mantoux Test and PSD Protocol
- Protocol and patient specific direction for the referral, authorisation, and administration of unlicensed bacillus calmette-guerin vaccine (bcg) for reduction of risk of tuberculosis infection

9 VERSION HISTORY TABLE

Not applicable as this is the first version

Version	Date	Author	Ratified by	Comment/Reason for change
1.0	03/12/2020	Ibrahim Hassan	MMC	

APPENDIX A – CONSULTATION TEMPLATE

1.	Procedural Document's Name:	Guidance on Vaccination Requirements in Adult Patients Starting Biologic Agents	
2.	Procedural Document Author:	Ibrahim Hassan	
3.	**Group/Committee Consulted**		**Date**
	Rheumatology Team- no comments received		22/07/2020
	Dermatology Team- no comments received		10/08/2020
	Gastroentrology Team- Comments received from Dr Gupta and Deirdre Braim- see below		
4	**Name and Title of Key Individuals Consulted**		**Date**
	Dr Sanjay Gupta- Consultant Gastroentrologist • The guidelines mention only BSR guidelines but none from ECCO or BSG and in my view should include all specilaities which use biologics – Actioned and also includes dermatology • I am not clear about administration of live zoster vaccine for JAK 2 patients who are seropositive or have had chicken pox in the past- why do they need a vaccine? Vaccine is required for those who are seronegative – The document has been amended this to make it clearer and now applies to all biologics as per the BSG IBD guidelines. • Latent (or active) TB exclusion should include a IGRA Quantiferon test which is mentioned in the appendix – Actioned		13/08/2020

	• There is no mention of HPV vaccine – this is because it is included in the UK immunisation schedule, see appendix B • There is no mention of Shingrix which is an attenuated varicella vaccine that can be administered to patients who are immunosuppressed - Shingrix is an unlicensed product imported from the EU, it costs over £500 and is not covered under the NHS. It would not be an option as Zostavax is already available as a licensed product. • I am not arae of BSR guidelines but for IBD patients, a dose of azatthioprine <3mg/Kg is considered to ne 'low dose' and pts can be given vaccine - Not included as guideline is for biologics only. • ECCO recommendations mention vaccination for Hep B before starting disease modifying drugs in pts who are serology negative. Rather than immunise all pts who are negative, those who are at risk of hepatitis B should be immunised prior to starting treatment as UK is a low prevalence country – Noted, however the SPC for the biologics recommend patient's should be tested for Hep B prior to initiation. • There should be a mention of giving live vaccines after the cessation of anti-TNFs, Vedo-can be given live vaccines without lag period - Not included as the purpose of the guideline is for vaccination requirements prior to starting a biologic	
	Deirdre Braim- Specialist Gastroentrology Nurse • We don't usually tell our patients to stop treatment when pregnant but to contact us as soon as they are aware.- This guideline excludes maternity patients • How receptive will the GPs be to give vaccinations if and when required?- The are able to arrange for patient vaccinations if clinically indicated	03/09/2020
	Claudette Allerdyce-Head of Medicines Optimisation (Croydon CC) Fluenz Tetra (Live influenza vaccine) is used in children, and documented on table 1. However, the guideline is related to adult only- The list on the table is revised Fluenz Tetra and Rotarix (Rotavirus vaccine) have been removed.	11/09/2020
	MMC members • General comment: This guideline should be reviewed by haematology for comments. Has been sent to Haematology Team but no comments received. • General comment: BSR guidance advises patients must have flu and pneumococcal vaccine however GPs have refused this based on nature of immunosuppressive therapy e.g. DMARD or biologic. There is a need to liaise with GPs via CPC to ensure their protocols on eligibility for treatment, have included patients on immunosuppressants and biologics. What about top up vaccines e.g. shingles? Action - This guideline should go to CPC for approval. CPC has approved the guideline on 13/11/2020 • Page 4 (Introduction – 1st paragraph): Why have we only done a guideline for biologics and not other immunosuppressive	05/10/2020

	therapy if PHE recommends assessment for vaccine eligibility in patients anticipating immunosuppressive therapy? It is because, this guidance is written to address the concerns made by our GPs, reporting patients on Biologics through Homecare but request has been made to prescribe it • Page 4 (Introduction- 2nd paragraph): Correct spelling of "Adalimumbab" to "Adalimumab" Done • Page 4 (Purpose): Change "Green Book" to the full name "Immunisation against infective disease" Done • Page 4 (Purpose): "Biologic" – decide if you want to capitalise the first letter, it would be better for this to be lowercase throughout the document. Done • Page 5 (table 1): Not all these are mentioned subsequently – is it worth differentiating between those on national schedule (which may therefore be required if topping up) and those which aren't? If we're just listing live vaccines available in UK, there are a few missing – Rotavirus, nasal flu (although they wouldn't normally be given to adults). This was removed on the recommendations of another reviewer (see consultation template). In addition, this guidance is for adult only. • Page 6 (bullet point 1): "Single dose injection (GPs will be advice if booster doses are required" – change to advised and state who will advise. This is deleted as it is not required. • Page 6 (Seasonal influenza): -This information should be in its own separate subheading/section, not incorporated into "vaccinations required prior to initiating a biologic agent" section. This is done -Change "October and January" to "September and March". This is done - "The annual letters on the influenza programme should be consulted for age eligibility" – State age or eligibility, not both. This is done • Page 6 (Vaccination of individuals with unknown or incomplete immunisation status): One thing not referenced or reproduced in an appendix is the Vaccination of Individuals with Uncertain or Incomplete Immunisation status document – this seems to me vital as this is how you will identify what top-ups are needed. I'd say this is at least as important if not moreso than the routine schedule listed in the appendix (only flu, shingles, and PPV are routinely given in adults, which is also included in the catch-up document) This is done • Page 6 (Vaccination of individuals with unknown or incomplete immunisation status – bullet point 3): Is there any value to suggesting checking in with the Rainbow centre? Particularly if the individual cannot explain their history for whatever reason? If seeking asylum its possible Rainbow will have vaccinated them already. This is done • Page 7 (Varicella Zoster Virus): General comment – where will this be done and who will do this? e.g. GP/hospital. GP • Page 7 (Varicella Zoster Virus – bullet point 1): Explain what happens after testing for VZV IgG, do you vaccinate if positive? The section is amended to make it clear • Page 7 (Varicella Zoster Virus – bullet point 2): - "Herpes zoster (HZ)" – clarify if this is the zoster vaccine i.e. Zostervax. -It must be clearly stated that many patients with be on immunosuppressant's, there will be stepping up to a biologic as an addition to their existing treatment and not necessarily stopping previous treatment. The BSR guideline states the doses of other immunosuppressant's that would preclude	

	patients from having the live vaccine – VZV. There are various recommendations depending on what drug the patient is on, patients are often on concurrent therapy. Need a separate step to show what happens if patients are on combination therapy which precludes them from having the live vaccine. The section is amended to make it clear • Page 7 (Varicella Zoster Virus – bullet point 3): "If a live zoster vaccine is administered; it should only be administered to patients with a known history of chickenpox or those that are seropositive for varicella zoster virus (VZV). If the history of chickenpox is considered doubtful or unreliable it is recommended to test for antibodies against VZV" - are we vaccinating those with previous chickenpox or VZV igG as they can get shingles, therefore we are trying to prime immune system against this happening? The section is amended to make it clear • Page 7 (Tuberculosis): Add "Patients must be referred to the respiratory team for latent TB screening before initiation of a new biologic agent. Upon referral, the patient will have the chest X ray, the mantoux test, the quantiferon test, the clinical assessment and decision made for treatment with antibiotics." This is done • Page 8 (Human Immunodeficiency Virus (HIV)): reference 2nd paragraph, is it from NICE? This is done • Page 8 (HBV and HCV): -Correct spelling of Hepatistis to Hepatitis. This is done -Add in brackets the risk factors next to "ongoing risk factors" This is done • Page 9 (Summary of processes for initiating a biologic therapy): "Patient is screened for TB, HBV or HCV, and cleared to be started on" This is done - Who does this? Do they need other services i.e. chest clinic for TB screen? This is done - Who is administering the vaccines? GP? How do we ensure they'll be done in a timely fashion, particularly if live, or if we are delaying the start of therapy. Check with patient/ carer, CyC and communicate with the patient's GP • Page 9 (Monitoring Compliance): Delete 1st paragraph "describe how compliance…." Also the table only shows how we check/update the guidelines, how are we going to monitor compliance with them in the clinics? This is done • Page 9 (references): remove live links, can input generic website name. This is done • Page 10 (Associated Documentation): Consider adding Mantoux testing protocol and PSD. This is done • Appendix A: -Clarify if rheumatology or dermatology had no comments or if a reply wasn't received. If the latter, to chase this up. Dr Rajak had reviewed at MMC -"I am not clear about administration of live zoster vaccine for JAK 2 patients who are seropositive or have had chicken pox in the past-why do they need a vaccine? Vaccine is required for those who are seronegative – The document has been amended this to make it clearer and now applies to all biologics as per the BSG IBD guidelines." - But it still says this!? And anyway vaccine isn't required for the seronegative, but the seropositive. The section is amended to make it clear - "ECCO recommendations mention vaccination for Hep B before starting disease modifying drugs in pts who are serology negative. Rather than immunise all pts who are negative, those	

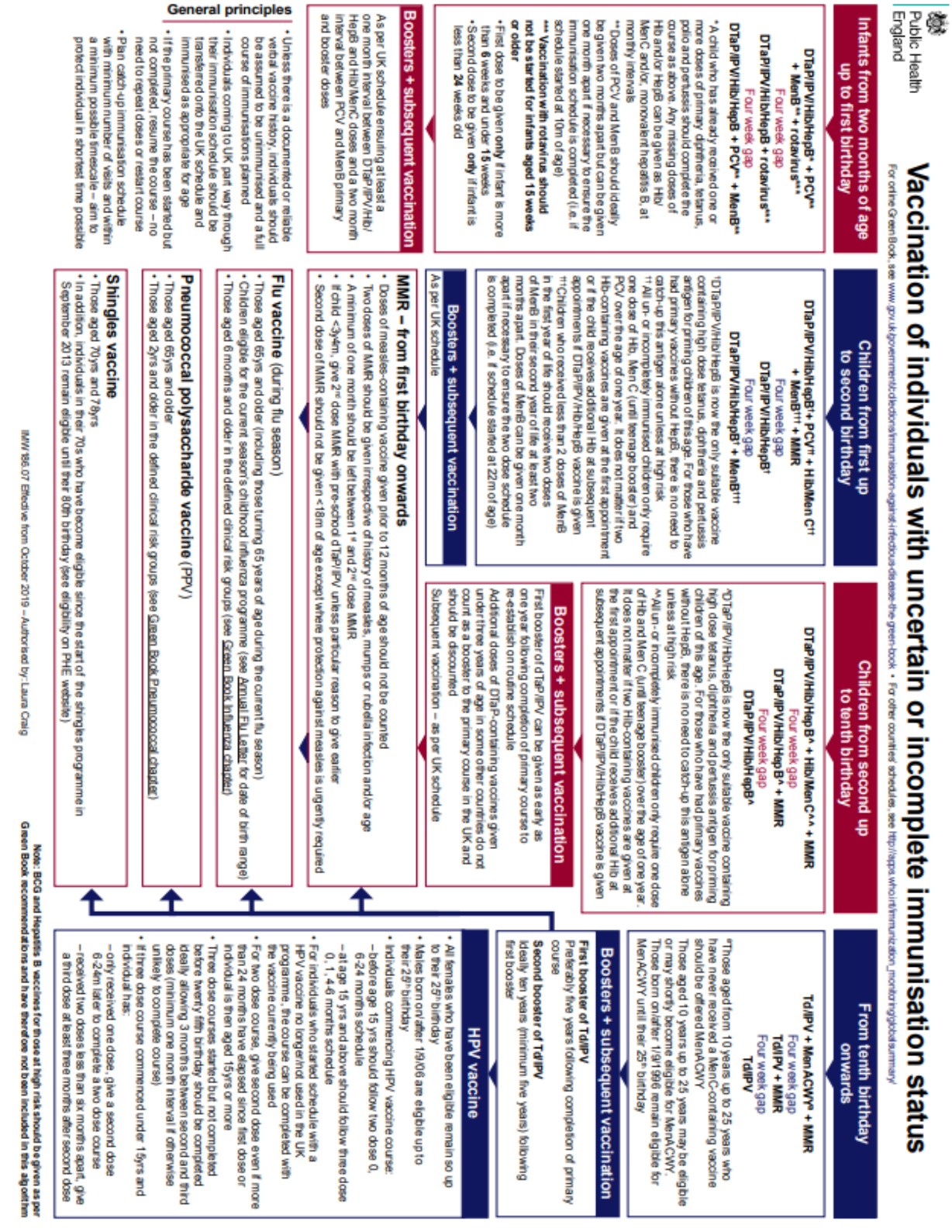
	who are at risk of hepatitis B should be immunised prior to starting treatment as UK is a low prevalence country – Noted, however the SPC for the biologics recommend patient's should be tested for Hep B prior to initiation." - Does it say they should all be immunised? And should we put what the SPC says in here if it contradicts guidelines from a specialist group? Is it worth the cost/delay to Tx? Also, BSR does not provide this recommendation; this requires a broader discussion, to look at the grade of evidence behind this. To discuss this between specialties to see if there is a consensus. This is clearly explained at the Hep B and C section on page 8 - Deirdre Braim- Specialist Gastroentrology Nurse – "How receptive will the GPs be to give vaccinations if and when required? - The are able to arrange for patient vaccinations if clinically indicated" - Are they able to get all of them? TB? Mantoux testing? No, just vaccination	

APPENDIX B – SCHEDULE FOR THE UK'S ROUTINE IMMUNISATION PROGRAMME (EXCLUDING CATCH-UP CAMPAIGNS)

Age due	Vaccine given	How it is given[1]
Eight weeks old	Diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type b (Hib) and hepatitis B (DTaP/IPV/Hib/HepB) Meningococcal B (MenB) Rotavirus	One injection One injection One oral application
Twelve weeks old	Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (DTaP/IPV/Hib/HepB) Rotavirus Pneumococcal conjugate vaccine (PCV13)	One injection One oral application One injection
Sixteen weeks old	Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (DTaP/IPV/Hib/HepB) Meningococcal B (MenB)	One injection One injection
One year old (on or after the child's first birthday)	Hib/MenC Pneumococcal conjugate vaccine (PCV13) Meningococcal B (MenB) Measles, mumps and rubella (MMR)	One injection[2] One injection[2] One injection[2] One injection[2]
Primary school age children (school years reception to six) Chapter 19)	Live attenuated influenza vaccine (LAIV)	Nasal spray, single application in each nostril (if LAIV is contraindicated and child is in a clinical risk group, give inactivated flu vaccine; see Chapter 19)
Three years four months old or soon after	Diphtheria, tetanus, pertussis and polio (dTaP/IPV) Measles, mumps and rubella (MMR)	One injection One injection
Twelve to thirteen years old	Human papillomavirus (HPV)	Course of two injections at least six months apart
Fourteen years old (school year 9)	Tetanus, diphtheria and polio (Td/IPV) Meningococcal ACWY conjugate (MenACWY)	One injection One injection
65 years old	Pneumococcal polysaccharide vaccine (PPV)	One injection
65 years of age and older	Inactivated influenza vaccine	One injection annually
70 years old	Shingles vaccine	One injection

Table taken from The Green Book(1)

APPENDIX C – Vaccination Schedule for individuals with incomplete vaccination status



APPENDIX D- BIOLOGICS INVESTIGATIONS AND VACCINATIONS CHECKLIST

This checklist must be completed and uploaded onto the patient's notes on CRS Millennium **before** starting an individual on a biologic agent.

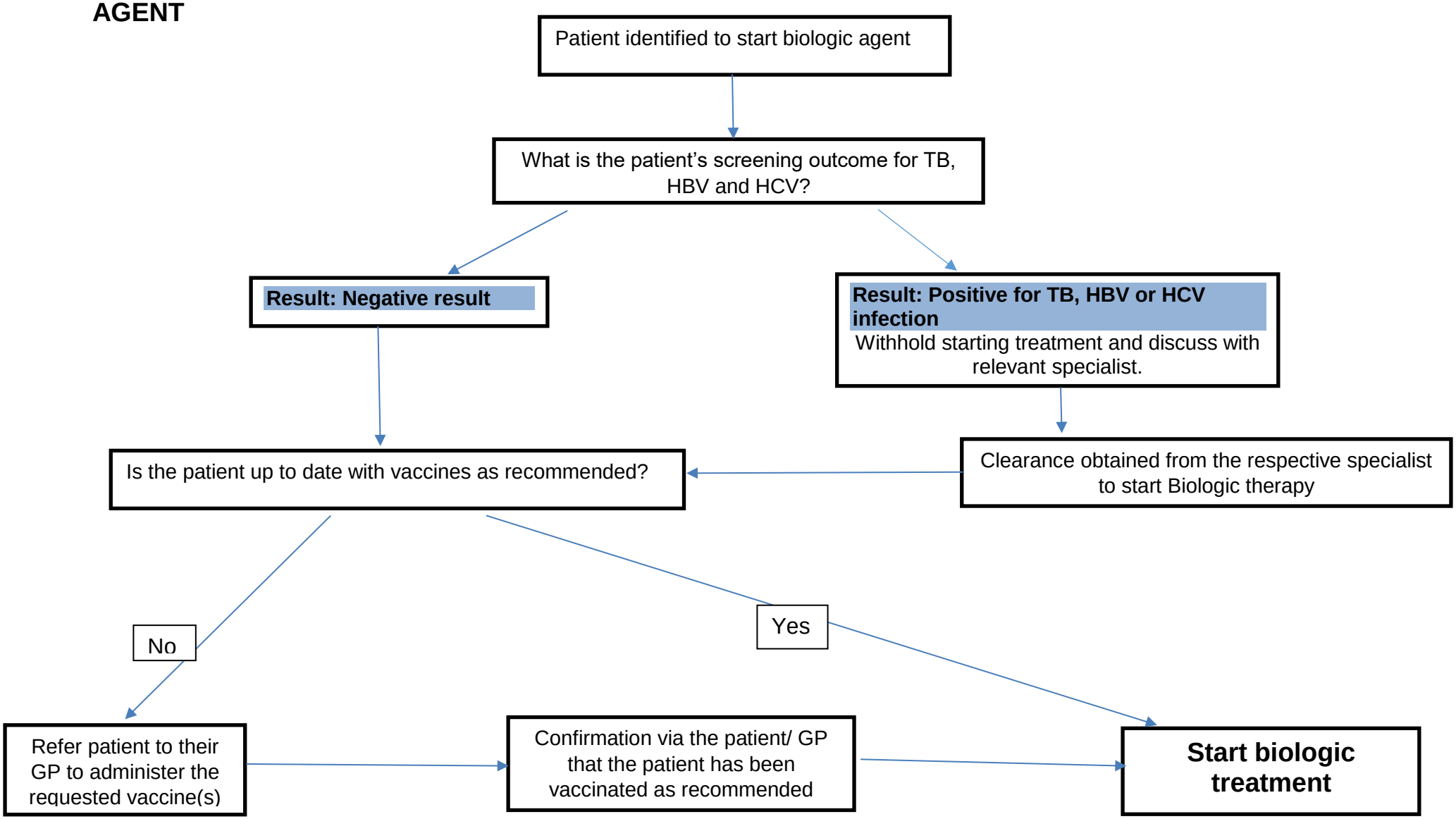
Note this checklist does not include routine screening such as full blood counts, urea and electroytes and renal function which should be completed prior to initiation – consult the manufacturers information.

Patient name:	Date:
Consultant/ Nurse name:	
Indication:	
Drug intended to start:	
Previous systemic medication:	
Other medication:	

Screening Investigations			
Tubercolosis Screening	**Y**	**N**	**Results/ Comments**
Chest X-Ray	Y	N	
Mantoux test	Y	N	
Quantiferon test	Y	N	
Refer **all** patients to local TB service with a history of previously treated TB, or who have had close contact with a case of active TB			
Hepatitis screening			
HBV	Y	N	
HCV	Y	N	
HIV Screening	Y	N	
Medication screening			
Is the patient taking any immunosuppressant treatment and requires a live vaccine?	Y	N	

Vaccination checklist			
Recommended pre-treatment vaccinations (if eligible)	**Y**	**N**	**Results/ Comments**
Up to date with the UK's routine immunisation programme	Y	N	If not, please document which vaccines the patient is required to have
Pneumococcal	Y	N	
Influenza	Y	N	
Shingles Vaccine or Chikenpox Vaccine	Y	N	

APPENDIX E – FLOWCHART HIGHLIGHTING THE TESTS REQUIRED PRIOR TO INITIATING A BIOLOGIC AGENT



APPENDIX F- BIOLOGIC INITIATION NOTIFICATION LETTER

Croydon Health Service
NHS Trust

Private and Confidential

Croydon University Hospital
530 London Road
Croydon
CR7 7YE
Switchboard Tel: (020) 8401 3000

Dear

Re:

You have been accepted for Biologic therapy, …Insert name of the biologic agent…….. We have passed your information onto the …Insert name of the Homecare company if via this route…company who will contact you within the next 3 – 4 weeks, to organise delivery of the drug to your home.

Following this a nurse from ……(Homecare company)…… will contact you approximately 1 -2 weeks later to organise a visit to teach you how to self-inject the drug. This injection is given every week.

You must not give yourself the injection:
If you have an infection, i.e. chest, urine or any other.
If you are taking antibiotics.
If you are having planned surgery stop the injections two weeks prior and restart when the wound is healed and no sign of an infection.
If you are considering starting a family you must stop this medication two weeks prior, this must be discussed at a clinic visit as there may be other medication to review.

Please inform us as soon as you have started the injections. An outpatient appointment may have to be adjusted we like to review you 3 months following the start of the injections.

You must have blood tests monthly after starting the injections. The blood forms will be enclosed, if you have not had some already.
Continue with all your medications and these will be discussed when you are next seen in the outpatient department.

If you have not had a Pneumovax vaccine ……..and insert the name of any other recommended vaccines…… injection, please organise to have one at your GP prior to starting the Biologic therapy.

Always carry a list of ALL MEDICATIONS on your person.

You will be given a telephone number to contact…….Insert name of the homecare company…….

If you have not heard from … Insert name of the homecare company …..4 weeks after receiving this letter, contact the rheumatology department through 020 8401 3881.

Yours sincerely

…….Name……..
Rheumatology Nurse Specialist

CC:
……GP Details including name and address……