

Evidenz-basierter Einsatz von Immunglobulinen

Literaturhinweise / Quellenangaben

1. Dalakas MC, SpäthPJ (eds.): Intravenous Immunoglobulins in the Third Millenium. Parthenon Publishing Group, New York, London; 2004
2. WHO model list of essential medicines – 21st list, 2019
<https://www.worldhealthsummit.org>
3. Patel DD, Bussel JB. Neonatal Fc receptor in human immunity: Function and role in therapeutic intervention. J Allergy Clin Immunol. 2020 Sep;146(3):467–478. doi: 10.1016/j.jaci.2020.07.015. PMID: 32896307.
4. Shapiro RS, Wasserman RL, Bonagura V, Gupta S. Emerging Paradigm of Primary Immunodeficiency Disease: Individualizing Immunoglobulin Dose and Delivery to Enhance Outcomes. J Clin Immunol. 2017 Feb;37(2):190–196. doi: 10.1007/s10875-014-9990-x. Epub 2014 Jan 30. PMID: 24477950
5. Sewell WA, Kerr J, Behr-Gross ME, Peter HH; Kreuth Ig Working Group. European consensus proposal for immunoglobulin therapies. Eur J Immunol. 2014 Aug;44(8):2207–14. doi: 10.1002/eji.201444700. PMID: 24975475
6. Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg). EMA/CHMP/BPWP/94038/2007 rev. 6. Date of coming into effect: 1st Jan. 2019; aktualisiert 1st Jan.2022
7. Core SmPC for human normal immunoglobulin for subcutaneous and intramuscular use (EMA/CHMP/BPWP/143744/2011 rev 1; aktualisiert 1st Sept.2015
8. European Public Assessment Report. HyQvia Product information 2021. Available at:
https://www.ema.europa.eu/en/documents/product-information/hyqvia-epar-product-information_en.pdf
9. Kivity S, Katz U, Daniel N, Nussinovitch U, Papageorgiou N, Shoenfeld y; Evidence for the use of intravenous immunoglobulins – a review of the literature; Clin Rev Allergy Immunol. 2010 Apr;38(2–3):201–69. doi: 10.1007/s12016-009-8155-9. PMID: 19590986;
10. Perez EE, Orange JS, Bonilla F, Chinen J, Chinn IK, Dorsey M, et al. Update on the use of immunoglobulin in human disease: a review of evidence. J Allergy Clin Immunol, 2017;139:S1–46. PMID: 28041678.
11. Brand A, De Angelis V, Vuk T, Garraud O, Lozano M, Politis D; European Mediterranean Initiative for Transfusion Medicine. Review of indications for immunoglobulin (IG) use: Narrowing the gap between supply and demand. Transfus Clin Biol. 2021 Feb;28(1):96–122. doi: 10.1016/j.traccli.2020.12.005. Epub 2020 Dec 13. PMID: 33321210.
12. Farrugia A. The interphase between immunoglobulin, the plasma industry and the public health, managing a finite resource. Transfus Clin Biol. 2021 Feb;28(1):86–88. doi: 10.1016/j.traccli.2020.12.004. Epub 2020 Dec 13. PMID: 33358661.
13. Strengers PF, Klein HG. Plasma is a strategic resource. Transfusion. 2016 Dec;56(12):3133–3137. doi: 10.1111/trf.13913. Epub 2016 Nov 12. Erratum in: Transfusion. 2017 Jul;57(7):1849. PMID: 27861951.
14. Hogan Levells. Immunoglobulin therapies in the US: How they are used. Round Table Report organized by PPTA. Sept. 9th 2021. www.hoganlevells.com
15. FDA Center for Biologics Research. Information about immune globulin (human) product shortage. FDA; 2019. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/information-about-immune-globulin-human-products/shortage>. Accessed August 10, 2020.

16. Prevot J, Jolles S. Global immunoglobulin supply: steaming towards the iceberg? *Curr Opin Allergy Clin Immunol*. 2020 Dec;20(6):557–564. doi: 10.1097/ACI.0000000000000696. PMID: 33044340.
17. Jolles, S, Michallet, M, Agostini, C, et al. Treating secondary antibody deficiency in patients with haematological malignancy: European expert consensus. *Eur J Haematol*. 2021; 106: 439– 449. <https://doi.org/10.1111/ejh.13580>
18. Khan S, Grimbacher B, Boecking C, Chee R, Allgar V, Holding S, Wong G, Huissoon A, Herriot R, Doré P, Sewell W. Serum trough IgG level and annual intravenous immunoglobulin dose are not related to body size in patients on regular replacement therapy. *Drug Metab Lett*. 2011 Apr;5(2):132–6. doi: 10.2174/187231211795305302. PMID: 21457142.
19. Kerr J, Quinti I, Eibl M, Chapel H, Späth PJ, Sewell WA, Salama A, van Schaik IN, Kuijpers TW, Peter HH. Is dosing of therapeutic immunoglobulins optimal? A review of a three-decade long debate in europe. *Front Immunol*. 2014 Dec 12;5:629. doi: 10.3389/fimmu.2014.00629. PMID: 25566244; PMCID: PMC4263903.
20. Lei WT, Chang LS, Zeng BY, Tu YK, Uehara R, Matsuoka YJ, Su KP, Lee PC, Cavalcante JL, Stubbs B, Lin PY, Wu YC, Hsu CW, Chen TY, Chen YW, Yeh PY, Sun CK, Tseng PT, Kao YH. Pharmacologic interventions for Kawasaki disease in children: A network meta-analysis of 56 randomized controlled trials. *EBioMedicine*. 2022 Apr;78:103946. doi: 10.1016/j.ebiom.2022.103946. Epub 2022 Mar 17. PMID: 35306339; PMCID: PMC8933672.
21. Howard JF Jr, Bril V, Vu T, Karam C, Peric S, Margania T, Murai H, Bilinska M, Shakarishvili R, Smilowski M, Guglietta A, Ulrichts P, Vangeneugden T, Utsugisawa K, Verschuuren J, Mantegazza R; ADAPT Investigator Study Group. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomized, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021 Jul;20(7):526–536. doi: 10.1016/S1474-4422(21)00159-9. Erratum in: *Lancet Neurol*. 2021 Aug;20(8):e5. PMID: 34146511.
22. Howard JF Jr, Utsugisawa K, Benatar M, Murai H, Barohn RJ, Illa I, Jacob S, Vissing J, Burns TM, Kissel JT, Muppidi S, Nowak RJ, O'Brien F, Wang JJ, Mantegazza R; REGAIN Study Group. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. *Lancet Neurol*. 2017 Dec;16(12):976–986. doi: 10.1016/S1474-4422(17)30369-1. Epub 2017 Oct 20. Erratum in: *Lancet Neurol*. 2017 Dec;16(12):954. PMID: 29066163.
23. Nelke C, Schroeter CB, Stascheit F, Pawlitzki M, Regner-Nelke L, Huntemann N, Arat E, Öztürk M, Melzer N, Mergenthaler P, Gassa A, Stetefeld H, Schroeter M, Berger B, Totzeck A, Hagenacker T, Schreiber S, Vielhaber S, Hartung HP, Meisel A, Wiendl H, Meuth SG, Ruck T. Eculizumab versus rituximab in generalised myasthenia gravis. *J Neurol Neurosurg Psychiatry*. 2022 May;93(5):548–554. doi: 10.1136/jnnp-2021-328665. Epub 2022 Mar 4. PMID: 35246490; PMCID: PMC9016243.
24. Canadian Bloods Services and National advisory Committee on Blood and Blood Products. The National Plan of Management of Shortages of Immunoglobulin Products – Interim Guidance. 2020-07-27. [https://www.nacblood.ca/resources/shortages-plan/The National Plan for Management of Shortages of Immunoglobulin Products Ig\) Interim Guidance_July 27 2020.Published.pdf](https://www.nacblood.ca/resources/shortages-plan/The%20National%20Plan%20for%20Management%20of%20Shortages%20of%20Immunoglobulin%20Products%20Ig%20Interim%20Guidance_July%2027%202020.Published.pdf)
25. Department of Health, NHS: Demand management plan for immunoglobulin use. PO Box 777, London SE1 6XH.
26. National Blood Authority Australia: Criteria for clinical use of intravenous immunoglobulins in Australia. 2nd Edition 2012.

27. Agence nationale de sécurité du médicament et des produits de santé (ANSM): Hiérarchisation des indications des immunoglobulines humaines polyvalentes 2019 France – Version Avril 2019.
https://archiveansm.integra.fr/var/ansm_site/storage/original/application/cafoa364869b-food17be79df959d4f3d.pdf
<https://www.ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Utilisation-de-simmunoglobulines-humaines-polyvalentes-Ig-dans-un-contexte-de-tensions-d'approvisionnement-point-sur-les-actions-mises-en-aeuvre-Point-d-Information>
28. Di Giorgio D, Traversa G, Trotta MP et al. Italian Medicines Agency – AIFA: Guidelines on the use of human immunoglobulins in case of shortages.
29. Henseler O. Bericht des Paul-Ehrlich-Instituts über die nach § 21 Transfusionsgesetz gemeldeten Daten. Bericht für das Jahr 2021. Verfügbar unter
https://www.pei.de/SharedDocs/Downloads/DE/regulation/meldung/21-tfg/21-tfg-berichte/2021-tfg-21-bericht.pdf?__blob=publicationFile&v=6
30. Arbeitskreis Blut, RKI: Anwendung von humanen Immunglobulinpräparaten bei Lieferengpässen. Bundesgesundheitsbl 66, 1184–1189 (2023).
<https://doi.org/10.1007/s00103-023-03759-4>
31. Richter-Kuhlmann, E. Immunglobulinpräparate: Zunehmend ein rares Gut
Dtsch Arztebl 2023; 120 (33–34): A-1370 / B-1179.
32. Peter HH, Ochs HD, Cunningham-Rundles C, Vinh DC, Kiessling P, Greve B, Jolles S. Targeting FcRn for immunomodulation: Benefits, risks, and practical considerations. J Allergy Clin Immunol. 2020 Sep;146(3):479–491.e5. doi: 10.1016/j.jaci.2020.07.016. PMID: 32896308; PMCID: PMC7471860.